James L. Gulley, M.D., Ph.D., F.A.C.P. Updated February 2011

DEMOGRAPHIC INFORMATION

Current Appointments

National Cancer Institute

2001-present Attending Physician, Medical Oncology Branch, Center for Cancer

Research, National Cancer Institute, National Institutes of Health,

Bethesda, MD

2011-present Director, Clinical Trials Group and Senior Investigator (Tenured),

Laboratory of Tumor Immunology and Biology, Center for Cancer Research, National Cancer Institute, National Institutes of Health,

Bethesda, MD

Hospital

Senior Staff Member with Admitting Privileges, National Institutes of Health Clinical Center, National Cancer Institute, National Institutes of Health, Bethesda, MD 20892 (credentialed since July 1998)

Staff Physician, Medical Oncology, National Naval Medical Center, Bethesda, MD 20889 (credentialed since January 1999)

Staff Physician, Medical Oncology, Walter Reed Army Medical Center, Washington, DC 20307 (credentialed since December 2003)

Contact Information

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Education and Training

1983-1987	B.A. (Chemistry), Southern Adventist University, Collegedale, TN. Graduated <i>Magna Cum Laude</i> and Southern Scholar
1987-1994	Ph.D. (Microbiology, research in tumor immunology), Loma Linda University, Loma Linda, CA
1987-1995	M.D., Medical Scientist Training Program, Loma Linda University, Loma Linda, CA
1995-1998	Internal Medicine Residency, Emory University, Atlanta, GA
1998-2000	Medical Oncology Fellowship, National Cancer Institute, Bethesda, MD
2000-2001	Senior Clinical Fellow, Laboratory of Tumor Immunology and Biology, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, MD

Professional Experience

2001-2006	Staff Clinician and Director, Clinical Immunotherapy Group, Laboratory of Tumor Immunology and Biology,, Medical Oncology Branch, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, MD
2006-2010	Senior Clinician and Director, Clinical Trials Group, Laboratory of Tumor Immunology and Biology, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, MD
2010-2011	Tenure Track Investigator and Director, Clinical Trials Group, Laboratory of Tumor Immunology and Biology, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, MD
2011-present	Senior (Tenured) Investigator and Director, Clinical Trials Group, Laboratory of Tumor Immunology and Biology, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, MD

Medical Licenses and Certifications

Medical license: State of Georgia, 1996 to 2007

Diplomate, National Board of Medical Examiners, 1996

Diplomate, Internal Medicine, American Board of Internal Medicine, 1999 Diplomate, Medical Oncology, American Board of Internal Medicine, 2000

Medical license: State of Maryland, 2001 to present DEA registration # D0056966, 2001 to present Advanced Cardiac Life Support, 1995 to 2007 Basic Cardiac Life Support, 1984 to present

RESEARCH ACTIVITIES

Peer-Reviewed Publications

- 1. Dahut W, Fedenko K, Noone M, Arlen P, **Gulley J**, Pluda J, Figg WD. A randomized phase II trial of docetaxel (Taxotere) plus thalidomide in androgen independent prostate cancer. *Adv Prostate Cancer*. 2001;5(1):8-10.
- 2. Zhu M, Terasawa H, **Gulley J**, Panicali D, Arlen P, Schlom J, Tsang K. Enhanced activation of human T cells via avipox vector-mediated hyperexpression of a triad of costimulatory molecules in human dendritic cells. *Cancer Res.* 2001;61(9):3725-3734.
- 3. von Mehren M, Arlen P, **Gulley J**, Rogatko A, Cooper HS, Meropol NJ, Alpaugh RK, Davey M, McLaughlin S, Beard MT, Tsang KY, Schlom J, Weiner LM. The influence of GM-CSF and prior chemotherapy on the immunologic response to a vaccine (ALVAC-CEA B7.1) in patients with metastatic carcinoma. *Clin Cancer Res*. 2001;7(5):1181-1191.
- 4. Figg WD, Arlen P, **Gulley J**, Fernandez P, Noone M, Fedenko K, Hamilton M, Parker C, Kruger EA, Puda J, Dahut WD. A randomized phase II trial of docetaxel (Taxotere) plus thalidomide in androgen independent prostate cancer. *Semin Oncol*. 2001;28(4 suppl 15):62-66.
- 5. Tsang KY, Zhu M, Even J, **Gulley J**, Arlen P, Schlom J. The infection of human dendritic cells with recombinant avipox vectors expressing a costimulatory molecule transgene (CD80) to enhance the activation of antigen-specific cytolytic T cells. *Cancer Res.* 2001;61(20):7568-7576.

- 6. Terasawa H, Tsang K, **Gulley J**, Arlen P, Schlom J. Identification and characterization of a human agonist epitope of human prostate-specific antigen. *Clin Cancer Res*. 2002;8(1):41-53.
- 7. **Gulley J**, Chen AP, Dahut W, Arlen PM, Bastian A, Steinberg S, Tsang K, Panicali D, Poole D, Schlom J, Hamilton JM. Phase I study of a vaccine using recombinant vaccinia virus expressing PSA (rV-PSA) in patients with metastatic androgen independent prostate cancer. *Prostate*. 2002;53(2):109-117.
- 8. Horne MK, Figg WD, Arlen PM, **Gulley J**, Parker C, Lakhani N, Parnes H, Dahut WD. Increased incidence of venous thromboembolism with the combination of docetaxel and thalidomide in patients with metastatic androgen-independent prostate cancer. *Pharmacotherapy*. 2003;23(3):315-318.
- 9. **Gulley J***, Arlen PM, Palena C, Marshall J, Schlom J, Tsang KY. A novel ELISPOT assay to enhance detection of antigen-specific T cells employing antigen-presenting cells expressing vector-driven human B7-1. *J Immunol Methods*. 2003;279(1-2):183-192.
- 10. Tsang K, Palena C, **Gulley J**, Arlen P, Schlom J. A human cytotoxic T-lymphocyte epitope and its agonist epitope from the non-variable number of tandem repeat sequence of MUC-1. *Clin Cancer Res.* 2004;10(6):2139-2149.
- 11. Tohnya T, Ng S, Dahut W, Wright J, Arlen P, **Gulley J**, Parker C, Zeldis J, Figg W. A phase I study of oral CC-5013 (lenalidomide, Revlimid®), a thalidomide derivative, in patients with refractory metastatic cancer. *Clin Prostate Cancer*. 2004;2(4):241-243.
- 12. Dahut WL, **Gulley JL**, Arlen PM, Liu Y, Fedenko KM, Steinberg SM, Wright JJ, Parnes H, Chen CC, Jones E, Parker CE, Linehan WM, Figg WD. Randomized phase II trial of docetaxel plus thalidomide in androgen-independent prostate cancer. *J Clin Oncol*. 2004;22(13):2532-2539.
- 13. Marshall JL, **Gulley JL**, Arlen PM, Beetham PK, Tsang KY, Slack R, Hodge JW, Doren S, Grosenbach DW, Hwang J, Fox E, Odogwu L, Park S, Panicali D, Schlom J. A phase I study of sequential vaccinations with fowlpox-CEA (6D)-TRICOM (B7.1/ICAM-1/LFA-3) alone and sequentially with vaccinia-CEA (6D)-TRICOM and GM-CSF in patients with CEA-expressing carcinomas. *J Clin Oncol*. 2005;23(4):720-731.
- 14. Figg WD, Liu Y, Arlen P, **Gulley J**, Fedenko K, Zhai S, Steinberg S, Lewis M, Dyer V, Chen C, Jones E, Forbes S, Kohler D, Trella A, Dahut WL. A randomized phase II trial of ketoconazole plus alendronate versus ketoconazole alone in patients with androgen-independent prostate cancer and bone metastases. *J Urol*. 2005;173(3):790-796.
- 15. Tsang K-Y, Palena C, Yokokawa J, Arlen PM, **Gulley JL**, Mazzara GP, Gritz L, Gómez Yafal A, Ogueta S, Greenhalgh P, Manson K, Panicali D, Schlom J. Analyses of recombinant vaccinia and fowlpox vaccine vectors expressing transgenes for two human

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- tumor antigens and three human costimulatory molecules. *Clin Cancer Res.* 2005;11(4):1597-1607.
- 16. **Gulley JL***, Figg WD, Carter J, Steinberg S, Sartor O, Higano CS, Petrylak DP, Chatta G, Hussain MH, Dahut WL. A prospective analysis of the time to normalization of serum androgens following 6 months of androgen deprivation therapy in patients on a randomized phase III clinical trial utilizing intermittent hormonal therapy. *J Urol*. 2005;173(5):1567-1571.
- 17. **Gulley JL**, Arlen PM, Bastian A, Morin S, Marte J, Beetham P, Tsang K-Y, Hodge JW, Ménard C, Coleman CN, Camphausen K, Sullivan F, Steinberg SM, Schlom J, Dahut W. Combining a recombinant cancer vaccine with standard definitive radiotherapy in patients with localized prostate cancer. *Clin Cancer Res.* 2005;11(9):3353-3362.
- 18. Arlen PM, **Gulley JL**, Morin S, Novik L, Rucker S, Bastian A, Marte J, Palena C, Tsang KY, Schlom J, Dahut W. Antiandrogen, vaccine and combination therapy in patients with nonmetastatic hormone refractory prostate cancer. *J Urol*. 2005;174(2):539-546.
- 19. Posadas EM, **Gulley JL**, Arlen PM, Trout A, Parnes HL, Wright J, Lee M-J, Chung E-J, Trepel EJ, Sparreboom A, Chen C, Jones E, Steinberg SM, Daniels A, Figg WD, Dahut WL. A phase II study of perifosine in androgen independent prostate cancer. *Cancer Biol Ther*. 2005;4:1133-1137.
- 20. Dahut WL, Lakhani NJ, **Gulley JL**, Arlen PM, Kohn EC, Kotz H, McNally D, Parr A, Nguyen D, Yang X, Steinberg SM, Venitz J, Sparreboom A, Figg WD. Phase I clinical trial of oral 2-methoxyestradiol, an antiangiogenic and apoptotic agent, in patients with solid tumors. *Cancer Biol Ther*. 2006;5:22-27.
- 21. Arlen PM, **Gulley JL**, Parker C, Skarupa L, Pazdur M, Panicali D, Beetham P, Tsang KY, Grosenbach D, Feldman J, Steinberg S, Tsang KY, Jones E, Chen C, Marte J, Schlom J, Dahut W. A randomized phase II study of concurrent docetaxel vaccine versus vaccine alone in metastatic androgen-independent prostate cancer. *Clin Cancer Res.* 2006;12(4):1260-1269.
- 22. Ménard C, Johann D, Lowenthal M, Muanza T, Sproull M, Ross S, **Gulley J**, Petricoin E, Coleman CN, Whiteley G, Liotta L, Camphausen K. Discovering clinical biomarkers of ionizing radiation exposure with serum proteomic analysis. *Cancer Res*. 2006;66(3):1844-1850.
- 23. Arlen P, Pazdur M, Skarupa L, Rauckhorst M, **Gulley J**. A randomized pilot phase II study of docetaxel alone or in combination with PANVACTM-V (vaccinia) and PANVACTM-F (fowlpox) in patients with metastatic breast cancer (NCI 05-C-0229). *Clin Breast Cancer*. 2006;7(2):176-179.

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- 24. Lattouf JB, Arlen PM, Pinto P, **Gulley JL***. A phase I feasibility study of an intraprostatic PSA-based vaccine in patients with prostate cancer with local failure after radiotherapy or clinical progression on androgen deprivation therapy in the absence of local definitive therapy. *Clin Genitourin Cancer*. 2006;5(1):89-92.
- 25. Ahlers CM, Camphausen K, Citrin D, Arlen PM, **Gulley JL**[†]. A pilot trial of a CEATRICOM based vaccine and radiation to liver metastasis in patients with CEA positive metastatic tumors. *Clin Colorectal Cancer*. 2006;6(1):72-75.
- 26. Wu SL, Jones E, **Gulley JL**, Arlen PM, Chen CC, Figg WD, Dahut WL. Routine interval computed tomography to detect new soft-tissue disease might be unnecessary in patients with androgen-independent prostate cancer and metastasis only to bone. *BJU Int*. 2007;99:525-528. *BJU Int* [Online Early. December 2006].
- 27. O'Mahony D, Morris JC, Quinn C, Gao W, Wilson WH, Gause B, Pittaluga S, Neelapu S, Brown M, Fleisher T, **Gulley JL**, Schlom J, Nussenblatt R, Albert P, Davis TA, Lowy I, Petrus M, Waldmann TA, Janik JE. A pilot study of CTLA-4 blockade after cancer vaccine failure in patients with advanced malignancy. *Clin Cancer Res*. 2007;13(3):958-964.
- 28. Yokokawa J, Bera TK, Palena C, Cereda V, Remondo C, **Gulley JL**, Arlen PM, Pastan I, Schlom J, Tsang KY. Identification of cytotoxic T-lymphocyte epitope(s) and its agonist epitope(s) of a novel target for vaccine therapy (PAGE4). *In J Cancer*. 2007;121(3):595-605.
- 29. Figg WD, Li H, Sissung T, Retter A, Wu S, **Gulley JL**, Arlen P, Wright JJ, Parnes H, Fedenko K, Latham L, Steinberg SM, Jones E, Chen C, Dahut W. Preclinical and clinical evaluation of estramustine, docetaxel and thalidomide combination in androgen independent prostate cancer. *BJU Int.* 2007;99:1047-1055.
- 30. Theoret MR, Arlen PM, Pazdur M, Dahut WL, Schlom J, **Gulley JL***. Phase I trial of an enhanced PSA-based vaccine and anti-CTLA-4 antibody in patients with metastatic androgen independent prostate cancer. *Clin Genitourin Cancer*. 2007;5:347-50.
- 31. Arlen PM, Skarupa L, Pazdur M, Seetharam M, Tsang KY, Grosenbach DW, Feldman J, Poole DJ, Litzinger M, Steinberg SM, Jones E, Chen C, Marte J, Parnes H, Wright J, Dahut W, Schlom J, **Gulley JL**. Clinical safety of a viral vector-based prostate cancer vaccine strategy. *J Urol*. 2007 Oct;178(4 Pt 1):1515-20.
- 32. Dahut WL, Scripture C, Posadas E, Jain L, **Gulley JL**, Arlen PM, Wright JJ, Yu Y, Cao L, Steinberg SM, Aragon-Ching JB, Venitz J, Jones E, Chen CC, Figg WD. A phase II clinical trial of sorafenib in androgen-independent prostate cancer. *Clin Cancer Res*. 2008:14;209-14.

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- 33. Yokokawa J, Cereda V, Remondo C, **Gulley JL**, Arlen PM, Steinberg SM, Schlom J, Tsang KY. Enhanced functionality of CD4+CD25highFoxP3+ regulatory T cells in the peripheral blood of prostate cancer patients. *Clin Cancer Res.* 2008;14(4):1032-1040.
- 34. Arlen PM, Bianco F, Dahut WL, D'Amico A, Figg WD, Freedland SJ, **Gulley JL**, Kantoff PW, Kattan MW, Lee A, Regan M, Sartor O. Prostate Specific Antigen Working Group guidelines on prostate specific antigen doubling time. *J Urol*. 2008;179:2181-2186.
- 35. **Gulley JL**, Arlen PM, Tsang K-Y, Yokokawa J, Palena C, Poole DJ, Remondo C, Cereda V, Jones JL, Pazdur MP, Steinberg SM, Dahut WL, Kotz H, Schlom J. A pilot study to evaluate the safety and clinical outcomes of vaccination with recombinant CEA-MUC-1-TRICOM (PANVAC) poxviral-based vaccines in patients with metastatic carcinoma. *Clin Cancer Res.* 2008;14(10):3060-9.
- 36. Sharifi N, Hamada A, Sissung T, Danesi R, Venzon D, Baum C, **Gulley JL**, Price DK, Dahut WL, Figg WD. A polymorphism in a transporter of testosterone is a determinant of androgen independence in prostate cancer. *BJU Int*, 2008;102(5):617-621.
- 37. Madan R, **Gulley JL**, Schlom J, Steinberg SM, Liewehr D, Dahut WL, Arlen PM. Analysis of overall survival in patients with nonmetastatic castrate-resistant prostate cancer treated with vaccine, nilutamide, and combination therapy: implications for clinical trial design. *Clin Cancer Res.* 2008 Jul 15;14(14):4526-31.
- 38. **Gulley JL***, Aragon-Ching JB, Steinberg SM, Hussain MH, Sartor O, Higano CS, Petrylak DP, Chatta GS, Arlen PM, Figg WD, Dahut WL. Kinetics of serum androgen normalization and factors associated with testosterone reserve after limited androgen-deprivation therapy in nonmetastatic prostate cancer. *J Urol*, 2008;180(4):1432-1437.
- 39. Lechleider RJ, Arlen PM, Tsang K-Y, Steinberg SM, Yokokawa J, Cereda V, Camphausen K, Schlom J, Dahut WL, **Gulley JL***. Safety and immunologic response of a viral vaccine to PSA in combination with radiation therapy when metronomic-dose IL-2 is used as an adjuvant. *Clin Cancer Res.* 2008;14(16):5284-5291.
- 40. Aragon-Ching JB, Jain L, **Gulley JL**, Arlen PM, Wright J, Steinberg S, Draper D, Venitz J, Jones E, Chen C, Figg W, Dahut W. Final analysis of a phase II trial using sorafenib for metastatic castration resistant prostate cancer. *BJU Int*, 2009;103(12):1636-1640.
- 41. Figg WD, Hussain MH, **Gulley JL**, Arlen PM, Aragon-Ching JB, Petrylak DP, Higano CS, Steinberg SM, Chatta GS, Parnes H, Wright JJ, Sartor O, Dahut WL. A double-blind randomized crossover study of oral thalidomide versus placebo for androgen dependent prostate cancer treated with intermittent androgen ablation. *J Urol*, 2009;181(3):1104-1113.

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- 42. Aragon-Ching JB, Ning YM, Chen CC, Latham L, Guadagnini JP, **Gulley JL**, Arlen PM, Wright JJ, Parnes H, Figg WD, Dahut WL. Higher incidence of osteonecrosis of the jaw (ONJ) in patients with metastatic castration-resistant prostate cancer treated with antiangiogenic agents. *Cancer Invest*. 2009;27(2):221-226.
- 43. Dahut W, Aragon-Ching J, Woo S, Tohnya T, **Gulley J**, Arlen P, Wright J, Figg W. A phase I study of oral lenalidomide in patients with refractory metastatic cancer. *J Clin Pharmacol*. 2009;46(6):650-660.
- 44. Aragon-Ching JB, Jain L, **Gulley JL**, Arlen PM, Wright JJ, Steinberg SM, Draper D, Venitz J, Jones J, Chen C, Figg WD, Dahut WL. Final analysis of a phase II trial using sorafenib for metastatic castration-resistant prostate cancer. *BJU Int*, 2009;103:1636-1640.
- 45. Cereda V, Poole DJ, Palena C, Das S, Bera TK, Remondo C, **Gulley JL**, Arlen PM, Yokokawa J, Pastan I, Schlom J, Tsang KY. New gene expressed in prostate: a potential target for T cell-mediated prostate cancer immunotherapy. *Cancer Immunol Immunother*, 2010;59:63–71.
- 46. Kamrava M, Tsang KY, Madan RA, Kaushal A, Coleman CN, **Gulley JL***. Long-term survival and PSA control with radiation and immunotherapy for node-positive prostate cancer. *Clin Dev Immunol* 2009;2009:363914. Epub 2010 Mar 8.
- 47. Ning YM, **Gulley JL**, Arlen PM, Woo S, Steinberg SM, Wright JJ, Parnes HL, Trepel JM, Lee MJ, Kim YS, Sun H, Madan RA, Latham L, Jones E, Chen CC, Figg WD, Dahut WL. Phase II trial of bevacizumab, thalidomide, docetaxel, and prednisone in patients with metastatic castration-resistant prostate cancer. *J Clin Oncol*. 2010;28:2070-2076.
- 48. Kantoff PW, Schuetz TJ, Blumenstein BA, Glode LM, Bilhartz DL, Panicali DL, Laus R, Schlom J, Dahut WL, Arlen PM, **Gulley JL**, Godfrey WR. Overall survival (OS) analysis of a Phase II randomized controlled trial (RCT) of a poxviral-based PSA targeted immunotherapy in metastatic castration-resistant prostate cancer (mCRPC). *J Clin Oncol* 2010 Mar 1;28(7):1099-105.
- 49. **Gulley JL**, Arlen PM, Madan RA, Tsang KY, Pazdur MP, Skarupa L, Jones JL, Poole DJ, Higgins JP, Hodge JW, Cereda V, Steinberg SM, Halabi S, Jones E, Chen C, Parnes H, Wright JJ, Dahut WL, Schlom JS. Immunologic and prognostic factors associated with overall survival employing a poxviral-based PSA vaccine in metastatic castrateresistant prostate cancer. *Cancer Immunol Immunother*. 2010;59(5):663-74. Epub 2009 Nov 5.
- 50. Figg WD, Woo S, Zhu W, Chen X, Ajiboye A, Steinberg SM, Price DK, Wright JJ, Parnes HL, Arlen PM, **Gulley JL**, Dahut WL. A phase I clinical study of high-dose

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- ketoconazole plus weekly docetaxel in metastatic castration-resistant prostate cancer. *J Urol*, 2010;183(6):2219-2226,
- 51. Nesslinger N, Ng A, Tsang KY, Ferrara TA, Schlom J, **Gulley JL**, Nelson BH. A viral vaccine encoding PSA induces antigen spreading to a common set of self proteins in prostate cancer patients. *Clin Cancer Res.* 2010;16(15):4046-4056.
- 52. Stein WD, **Gulley JL**, Schlom J, Madan RA, Dahut WL, Figg WD, Ning Y, Arlen PM, Price DK, Bates SE, Fogo AT. Tumor regression and growth rates determined in five intramural NCI prostate cancer trials. The growth rate as an indicator of therapeutic efficacy. *Clin Cancer Res*, 2011;17(4):907-917.
- 53. Vergati M, Cereda V, Madan RA, **Gulley JL**, Huen NY, Rogers CJ, Hance KW, Arlen PM, Schlom J, Tsang KY. Analysis of circulating regulatory T cells in patients with metastatic prostate cancer pre- vs. post-vaccination. *Cancer Immunol Immunother*, 2011;60(2):197-206.
- 54. Smith HA, Maricque BB, Eberhardt J, Petersen B, **Gulley JL**, Schlom J, McNeel DG. IgG responses to tissue-associated antigens as biomarkers of immunological treatment efficacy. *J Biomed Biotechnol*, 2011;2011:454861.
- 55. Tanno T, Rabel A, Alleyne M, Lee YT, Dahut WL, **Gulley JL**, Miller JL. Hepcidin, anemia, and prostate cancer [letter]. *BJU Int*, 2011;107(4):678-679.
- 56. Cereda V, Vergati M, Huen N, Bari MG, Jochems C, Intrivici C, **Gulley JL**, Apelian D, Schlom J, Tsang KY. Maturation of human dendritic cells with Saccharomyces cerevisiae (yeast) reduces the number and function of regulatory T cells and enhances the ratio of antigen-specific effectors to regulatory T cells. *Vaccine*, 2011. [Epub ahead of print]

Submitted

- 1. Kamrava M, Kesarwala AH, Madan R, Lita E, Kaushal A, Tsang KY, Steinberg S, Ferrara T, Dahut W, Schlom J, **Gulley JL.*** Long-Term Follow-Up of Prostate Cancer Patients Treated with Vaccine and Definitive Radiation Therapy, submitted.
- 2. Mohebtash M, Tsang K, Madan RA, Huen N, Poole DJ, Jochems C, Jones J, Ferrara T, Arlen PM, Pazdur M, Rauckhorst M, Jones EC, Dahut WL, Schlom J, **Gulley JL**. Clinical outcomes following immunotherapy with a MUC-1/CEA/TRICOM poxviral-based vaccine in patients with metastatic breast and ovarian cancer, submitted.
- 3. **Gulley JL**, Madan RA, Heery CR, Walter BA, Merino MJ, Vergati M, Poole DJ, Cereda V, Tsang K, Dahut WL, Schlom J, Pinto PA. A phase I study of intraprostatic administration of PSA-TRICOM vaccine in men with locally recurrent or progressive prostate cancer, submitted.

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- 4. Madan RA, Tsang K, Bilusic M, Vergati M, Poole D, Jochems C, Schlom J, Giaccone G, Gulley JL. Effect of talactoferrin alfa on the immune system in adults with non-small cell lung cancer (NSCLC), submitted.
- 5. Madan RA, Mohebtash M, Arlen PM, Vergati M, Rauckhorst M, Steinberg SM, Tsang KY, Poole DJ, Dahut WL, Schlom J, **Gulley JL**. A phase I trial of ipilimumab and a poxviral vaccine targeting PSA in metastatic castration-resistant prostate cancer: analysis of toxicity, response, and survival, submitted.

Other Publications (Book Chapters, Invited Reviews, etc.)

- 1. **Gulley J***, Arlen P, Dahut W. Treating systemic prostate cancer: emerging targets and therapies. *Emerg Ther Targets*. 2000;4(6):751-763.
- 2. **Gulley J**, Takimoto C. Pancreatic cancer. In: Abraham J, Allegra C, eds. *The Bethesda Handbook of Clinical Oncology*. Philadelphia: Lippincott Williams & Wilkins; 2001:107-112.
- 3. **Gulley J**, Figg WD, Dahut WL. Docetaxel plus thalidomide in a patient with androgen-independent prostate cancer. *Case Studies Prostate Cancer*. March 2002;1(1):1-7.
- 4. **Gulley J***, Dahut W. Novel clinical trials in androgen independent prostate cancer. *Clin Prostate Cancer*. 2002;1(1):51-57.
- 5. Arlen PM, Figg WD, **Gulley J**, Cox MC, Linehan WM, Dahut W. NCI intramural approach to advanced prostate cancer. *Clin Prostate Cancer*. 2002;1(3):153-162.
- 6. **Gulley J**, Figg WD, Dahut WL. Treatment options for androgen independent prostate cancer. *Clin Adv Hematol Oncol*. 2003;1(1):49-57.
- 7. Behrens RJ, **Gulley JL**, Dahut WL. Pulmonary toxicity during prostate cancer treatment with docetaxel and thalidomide. *Am J Ther*. 2003;10(3):228-232.
- 8. Arlen PM, **Gulley JL**, Tsang K, Schlom J. Strategies for the development of PSA-based vaccines for the treatment of advanced prostate cancer. *Exp Rev Vaccines*. 2003;2(4):483-493.
- 9. Rutter JL, Rao RS, Bouchelet I, Dores G, Green H, **Gulley JL**, Koblinski J, Lundberg M, Stolzenberg-Soloman R, Wheelock R, Williams W, Wolfsberg T, Graubard B, Hartge P, Wacholder S, Schwartz JP. Survey of mentoring experiences of NIH postdoctoral fellows. Available at: http://felcom.nih.gov/Mentoring/Mentor_revised_081403.pdf

- 10. Leonard GD, Dahut WL, **Gulley JL**, Arlen PM, Figg WD. Docetaxel and thalidomide as a treatment option in androgen independent prostate cancer. *Rev Urol*. 2003;5 Suppl 3:S65-S70.
- 11. **Gulley JL***, Dahut WL. Novel approaches to treating the asymptomatic hormone refractory prostate cancer patient. *Urology*. 2003;62 Suppl 6B:147-154.
- 12. Posadas EM, Dahut WL, **Gulley J***. The emerging role of bisphosphonates in prostate cancer. *Am J Ther*. 2004;1(1):60-73.
- 13. Arlen PM, **Gulley JL**, Dahut WL. Vaccine therapy for a patient with androgen-insensitive prostate cancer without evidence of measurable disease on scans. *Am J Ther*. 2004;11(3):238-241.
- 14. Retter A, **Gulley JL**, Dahut WL. Novel therapies for prostate cancer. *Cancer Biol Ther*. 2004;3(4):371-376.
- 15. **Gulley JL***, Dahut WL. Chemotherapy for prostate cancer: finally an advance. *Am J Ther*. 2004;11:288-294.
- 16. Arlen PM, **Gulley JL**. Therapeutic vaccines for colorectal cancer: a review of clinical data. *Am J Cancer*. 2004;3(5):299-316.
- 17. Schlom J, Palena C, Greiner JW, Tsang KY, Grosenbach DW, Sabzevari H, **Gulley JL**, Arlen PM, Kass E, Hodge JW. Combinatorial vaccine strategies and the use of molecular arrays to characterize T-cell activation development of therapeutic cancer vaccines. *Dev Biol (Basel)*. 2004;116:27-47.
- 18. **Gulley J**, Arlen P, Schlom J. Pox viral vaccines. In: Morse M, Clay T, Lyerly HK, eds. *Handbook of Cancer Vaccines*. Totowa, NJ: Humana Press; 2004:175-191.
- 19. Arlen P, **Gulley J**, Odogwu L, Marshall JL. Vaccines for the treatment of cancer. In: Figg W, McLeod H, eds. *Pharmacokinetics and Pharmacodynamics of Anti-Cancer Drugs*. Totowa, NJ: Humana Press; 2004:457-473.
- 20. **Gulley JL**, Dahut WL. Novel schedules of hormone therapy for prostate cancer. In: Devita V, Hellman S, Rosenberg S, eds. *Progress in Oncology*. Boston: Jones and Bartlett; 2004:236-253.
- 21. Arlen PM, **Gulley JL**. Docetaxel-based regimens, the standard of care for metastatic androgen insensitive prostate cancer. *Future Oncol*. 2005;1(1):19-22.
- 22. Todd NF, Lieberman R, **Gulley JL**, Dahut W, Arlen PM. Prolonged response to nilutamide in a patient with stage D0.5 prostate cancer who previously failed androgen deprivation therapy. *Am J Ther*. 2005;12(2):172-174.

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- 1. **Gulley JL***. PSA, a target for immunotherapy. *Encyclopedia of Cancer Targets*, submitted.
- 2. **Gulley JL***, Drake CG. Immunotherapy for Prostate Cancer: Recent Advances, Lessons Learned, and Areas for Further Research. *Clin Cancer Res*, submitted.
- 3. Madan RA, Ferrara TA, **Gulley JL***. Therapeutic Cancer Vaccines: An Emerging Approach to Cancer Treatment. Handbook of Anticancer Agents: Pharmacokinetics and Pharmacodynamics, submitted.

Books Edited

- 1. Abraham J, **Gulley JL**, Allegra C, eds. *Bethesda Handbook of Clinical Oncology*. 2nd ed. Philadelphia: Lippincott Williams & Wilkins: ©2005.
- 2. **Gulley JL**, Dahut WL, Moul JW, Sandler HM eds. *Prostate Cancer: A Clinical Guide*. 1st ed. Philadelphia: Lippincott Williams & Wilkins; ©2008.
- 3. Abraham J, **Gulley JL**, Allegra C, eds. *Bethesda Handbook of Clinical Oncology*. 3rd ed. Philadelphia: Lippincott Williams & Wilkins: ©2010.

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Clinical Protocols (Total Trials 52; Chair or PI 22)

Intramural (CCR) Studies

Associate Investigator: <u>NCI 00-C-0033</u> A randomized phase II trial of weekly docetaxel plus thalidomide versus weekly docetaxel in metastatic androgen independent prostate cancer.

Associate Investigator: <u>NCI 00-C-0052</u> A randomized phase II study of high-dose ketoconazole plus alendronate versus high-dose ketoconazole in patients with androgen independent metastatic prostate cancer.

Associate Investigator: <u>NCI 00-C-0080</u> A double blind randomized crossover phase III study of oral thalidomide versus placebo in patients with stage D0 androgen dependent prostate cancer following limited hormonal ablation.

Associate Investigator: <u>NCI 00-C-0137</u> A randomized phase II study of either immunotherapy with a regimen of recombinant pox viruses that express PSA/B7.1 + adjuvant GM-CSF and IL-2 or hormone treatment with nilutamide in patients with hormone refractory prostate cancer and no radiographic evidence of disease.

Protocol Chair: NCI 00-C-0154 A randomized phase II study of a PSA-based vaccine in patients with localized prostate cancer receiving standard radiotherapy.

Associate Investigator: <u>NCI 01-C-0256</u> A phase I trial of 2-methoxyestradiol (2ME₂), (NSC-659853) an angiogenesis inhibitor, in patients with solid tumors.

Medically Responsible Investigator: <u>NCI 02-C-0083</u> A multidose phase I study of oral CC5013, a thalidomide derivative, in patients with refractory metastatic cancer.

Associate Investigator: <u>NCI 02-C-0149</u> A phase I trial of high-dose ketoconazole plus weekly docetaxel in metastatic androgen-independent prostate cancer.

Principal Investigator: NCI 02-C-0179 Collection of blood from patients with cancer.

Associate Investigator: <u>NCI 02-C-0218</u> A pilot trial of concurrent docetaxel and a pox vector PSA vaccine followed by docetaxel in metastatic androgen independent prostate cancer.

Associate Investigator: <u>NCI 02-C-0284</u> A phase II pilot study of monoclonal antibody CTLA-4 in patients with follicular or mantle cell lymphoma, colon cancer, or prostate cancer refractory to vaccine therapy.

Associate Investigator: <u>NCI 03-C-0005</u> A pilot study of sequential vaccinations with recombinant vaccinia-CEA(6D)-TRICOM, and recombinant fowlpox-CEA(6D)-TRICOM (B7.1/ICAM-1/LFA-3) with sargramostim (GM-CSF), in conjunction with standard adjuvant chemotherapy in high-risk breast cancer patients.

Associate Investigator: <u>NCI 03-C-0040</u> Vaccine therapy before and after dose-intensive induction chemotherapy plus immune-depleting chemotherapy in treating patients with metastatic breast cancer.

Associate Investigator: <u>NCI 03-C-0157</u> A phase II study of perifosine in patients with metastatic androgen-independent prostate cancer.

Principal Investigator: <u>NCI 03-C-0176</u> A phase I/II pilot study of sequential vaccinations with rFowlpox-PSA(L155)-TRICOM (PROSTVAC-F/TRICOM) alone, or in combinations with rVaccinia-PSA(L155)-TRICOM (PROSTVAC-V/TRICOM), and the role of GM-CSF, in patients with prostate cancer.

Associate Investigator: <u>NCI 04-C-0132</u> A phase II trial combining estramustine, docetaxel and thalidomide in patients with androgen-independent metastatic prostate cancer.

Principal Investigator: <u>NCI 04-C-0167</u> A pilot trial of a CEA-TRICOM-based vaccine and radiation to liver metastasis with or without celecoxib, in patients with CEA-positive solid tumors.

Principal Investigator: <u>NCI 04-C-0246</u> An open label pilot study to evaluate the safety and tolerability of PANVAC-V (vaccinia) and PANVAC-F (fowlpox) in combination with sargramostim in adults with metastatic carcinoma.

Protocol Chair: NCI 04-C-0252 A pilot trial of recombinant fowlpox (rF)-CEA(6D)-TRICOM, recombinant vaccinia (rV)-CEA(6D)-TRICOM, and rF-GM-CSF in combination with combined chemotherapy/radiotherapy in patients with unresectable stage III non-small cell lung cancer.

Associate Investigator: <u>NCI 04-C-0257</u> A phase II trial of docetaxel, thalidomide, prednisone, and bevacizumab in patients with androgen-independent prostate cancer.

Associate Investigator: <u>NCI 04-C-0262</u> A phase II study of BAY 43-9006 (sorafenib) in metastatic, androgen-independent prostate cancer.

Principal Investigator: <u>NCI 04-C-0274</u> Follow-up study of subjects previously enrolled in immunotherapy studies utilizing gene transfer.

Associate Investigator: <u>NCI 04-C-0280</u> Randomized, crossover, pharmacokinetic study of paclitaxel (Taxol) and ABI-007 (a Cremophor EL-free, protein stabilized, nanoparticle paclitaxel) in patients with advanced solid tumors.

Principal Investigator: NCI 05-C-0017 A phase I feasibility study of an intraprostatic PSA-based vaccine in men with prostate cancer and local failure following radiotherapy

or cryotherapy or clinical progression on androgen-deprivation therapy in the absence of local definitive therapy.

Principal Investigator: <u>NCI 05-C-0167</u> Phase I trial of a PSA-based vaccine and an anti-CTLA-4 antibody in patients with metastatic androgen-independent prostate cancer.

Principal Investigator: <u>NCI 05-C-0229</u> A randomized pilot phase II study of docetaxel alone or in combination with PANVAC-V (vaccinia) and PANVAC-F (fowlpox) in patients with metastatic breast cancer.

Associate Investigator: <u>NCI 07-C-0059</u> A phase II study of AZD2171 in metastatic androgen-independent prostate cancer.

Associate Investigator: <u>NCI 07-C-0100</u> Collection of blood from patients with prostate cancer.

Principal Investigator: <u>NCI 07-C-0106</u> A randomized phase 2.5 study of ¹⁵³Sm-EDTMP (Quadramet) with or without a PSA/TRICOM vaccine in men with androgen-insensitive metastatic prostate cancer.

Principal Investigator: <u>NCI 07-C-0107</u> A randomized phase II trial combining vaccine therapy with PROSTVAC/TRICOM and flutamide vs. flutamide alone in patients with androgen-insensitive, nonmetastatic (D0.5) prostate cancer.

Principal Investigator: <u>NCI 07-C-0188</u> A double-blind randomized phase 2.5 trial of ONY-P1 vaccine vs. placebo in men with D0 prostate cancer following limited androgen ablation.

Principal Investigator: NCI 07-C-1234 Special exemption, 05-C-0167, a phase I trial of a PSA-based vaccine in an adult with metastatic androgen-independent prostate cancer.

Principal Investigator: <u>NCI 07-C-N214</u> Data analysis for 00-C-0154, a randomized phase II study of a PSA-based vaccine in patients with localized prostate cancer receiving standard radiotherapy.

Associate Investigator: <u>NCI 08-C-0039</u> A phase II study of ZD6474 (vandetanib) in subjects with advanced clear cell renal carcinoma.

Associate Investigator: <u>NCI 08-C-0074</u> A phase II study of satraplatin and prednisone in metastatic androgen-independent prostate cancer (AIPC).

Associate Investigator: <u>NCI 08-C-0083</u> Registration phase III study of Lucanix (belagenpumatucel-L) in advanced non-small cell lung cancer: an international, multicenter, randomized, double-blinded, placebo-controlled study of Lucanix maintenance therapy for stages III/IV NSCLC subjects who have responded to or have

stable disease following one regimen of front-line, platinum-based combination chemotherapy.

Principal Investigator: <u>NCI 08-C-0166</u> An open label pilot study to evaluate the effect on the immune system of talactoferrin in adults with non-small cell lung cancer (NSCLC).

Associate Investigator: <u>NCI 09-C-0018</u> A phase III, randomized, double-blinded, placebo-controlled study of oral talactoferrin in addition to best supportive care in adults with non-small cell lung cancer (NSCLC) who have failed two or more prior treatment regimens.

Principal Investigator: NCI 09-C-0101 An open label phase I study to evaluate the safety and tolerability of a vaccine (GI-6207) consisting of whole, heat-killed recombinant *Saccharomyces cerevisiae* (yeast) genetically modified to express CEA protein in adults with metastatic CEA-expressing carcinoma.

Associate Investigator: <u>NCI 09-C-0119</u> A phase I trial of AVN944, an IMPDH inhibitor, in adults with advanced-stage solid tumors.

Associate Investigator: <u>NCI 09-C-0139</u> A pilot study of vaccination with epitope-enhanced TARP peptide and TARP peptide-pulsed dendritic cells in the treatment of stage D0 prostate cancer.

Associate Investigator: <u>NCI 09-C-0195</u> A phase II trial of bevacizumab, lenalidomide, docetaxel, and prednisone (ART-P) for treatment of metastatic castrate-resistant prostate cancer.

Associate Investigator: <u>NCI 10-C-0062</u> A Phase I/II Study of TRC105 in Metastatic Castrate Resistant Prostate Cancer (CRPC)

Associate Investigator: <u>NCI 11-C0021</u> A pilot study of F-18 sodium fluoride PET/CT for metastatic burden quantification in prostate cancer.

Lead Associate Investigator: <u>NCI 11-C-XXXX</u> (pending) Phase I study of chitosan/IL-12 for the treatment of superficial bladder cancer in patients who have failed BCG treatment.

Principal Investigator: <u>NCI 11-C-XXXX</u> (pending) First in-human phase I trial of NHS-IL12 in patients with metastatic solid tumors

Associate Investigator: <u>NCI 11-C-XXXX</u> (pending) A pilot study of Stimuvax in combination with standard androgen deprivation therapy and radiation therapy for newly diagnosed, high risk prostate cancer patients

Principal Investigator: NCI 11-C-XXXX (pending) An open label phase I study to evaluate the safety and tolerability of a vaccine (Yeast-Brachyury) consisting of whole, heat-killed recombinant *Saccharomyces cerevisiae* (yeast) genetically modified to express Brachyury protein in adults with metastatic carcinoma.

Extramural Studies

NCI Co-Chair: <u>ECOG 1805</u> Eastern Cooperative Oncology Group PARADIGM: A Phase III Study of a PSA Vaccine in Androgen Ablation-Refractory Prostate Cancer with Absence of Metastatic Disease and GM-CSF (in review).

Co- Principal Investigator: <u>ECOG 1809</u> Phase II study of vaccine followed by standard chemotherapy vs. standard chemotherapy in patients with metastatic castration-resistant prostate cancer (open).

Principal Investigator: <u>BNIT-PRV-301</u> A Randomized, Double-blind, Phase 3 Efficacy Trial of PROSTVAC with or without GM-CSF in Men With Early Metastatic, Castrate-Resistant Adenocarcinoma of the Prostate (in review, scheduled to open August 2011).

Collaborators

NIH

- 1. William Dahut, Chief, GU/Gyn Section, MOB, and Clinical Director, CCR
 - Multiple prostate cancer clinical trials.
- 2. William "Doug" Figg, Head, Molecular Pharmacology Section, MOB, CCR
 - Multiple prostate cancer trials.
- 3. Giuseppe Giaccone, Head, Thoracic Oncology Section, MOB, CCR
 - Immunotherapy trials in thoracic oncology.
- 4. Tito Fojo, Head, Experimental Therapeutics Section, Senior Investigator, MOB, CCR
 - Tumor growth rate kinetics in patients on prostate cancer immunotherapy trials.
- 5. Peter Pinto, Staff Clinician, UOB, CCR
 - Intraprostatic vaccine trial and chitosan/IL-12 superficial bladder cancer trial.
- 6. Kevin Camphausen, Head, Imaging and Molecular Therapeutics Section, ROB, CCR
 - External beam radiation plus vaccine clinical trials.
- 7. Clara Chen, Head, Nuclear Medicine Department, NIH Clinical Center
 - Quadramet plus vaccine clinical trial and bone scintigraphy analysis on patients on vaccine clinical trials.
- 8. Peter Choyke, Program Director, MIP, CCR
 - Imaging studies in clinical trials of prostate cancer.
- 9. Ron Gress, Head, Transplantation Therapy Section, ETIB, CCR
 - TREC analysis in patients treated with androgen-deprivation therapy.
- 10. Jay Berzofsky, Head, Molecular Immunogenetics and Vaccine Research Section, VB, CCR
 - Trial of vaccine in prostate cancer patients with biochemical failure following local therapy.
- 11. Elizabeth Jones, Head, Department of Radiology, NIH Clinical Center

- Thymic index analysis for patients treated with androgen-deprivation therapy and RECIST tumor measurement analysis on patients treated on vaccine clinical studies.
- 12. Maria Merino, Senior Investigator, Laboratory of Pathology, CCR
 - Immunohistochemistry of intraprostatic vaccine clinical trial.
- 13. Jeff Gildersleeve, Senior Investigator, Chemical Biology Laboratory, SAIC-Frederick/NCI
 - Humoral responses in patients with prostate cancer treated on LTIB studies.

Academics

- 1. Edwin Posadas, Assistant Professor of Medicine, Section of Urology, The University of Chicago Medical Center
 - U Chicago site PI for the multicenter Quadramet clinical trial.
- 2. Mark Stein, Assistant Professor of Medicine, University of Medicine & Dentistry of New Jersey/The Cancer Institute of New Jersey
 - CINJ site PI for the multicenter Quadramet clinical trial.
- 3. Ned Lattime, Professor of Surgery, University of Medicine & Dentistry of New Jersey/The Cancer Institute of New Jersey
 - Intravesical administration of rF-GM-CSF and rF-TRICOM as well as intratumoral pancreatic cancer treatment with PANVAC.
- 4. Nuhad Ibrahim, Professor, Department of Breast Medical Oncology, Division of Cancer Medicine, The University of Texas M. D. Anderson Cancer Center
 - MD Anderson site PI for the multicenter PANVAC plus docetaxel clinical trial.
- 5. Douglas McNeel, Associate Professor, Department of Medicine, University of Wisconsin
 - Multicenter ECOG study of vaccine followed by docetaxel vs docetaxel alone in patients with metastatic CRPC.
- 6. Brad Nelson, Director, Deeley Research Centre, British Columbia Cancer Agency
 - Humoral responses in patients with localized prostate cancer following radiation with or without vaccine.
- 7. Chandan Guha, Professor, Department of Radiation Oncology, Albert Einstein College of Medicine
 - Trial of PANVAC plus radiochemotherapy in patients with locally advanced pancreatic cancer.
- 8. Michael Morse, Medical Co-Director, Duke Clinical Research-Oncology, Duke University Health System
 - Trial of PANVAC in patients with metastatic CRC following metastectomy.
- 9. William Carson, Professor of Surgery, Associate Director for Clinical Research, Ohio State University Comprehensive Cancer Center
 - Clinical trial of CEA-TRICOM plus interferon in patients with CRC.
- 10. Robert DiPaola, Associate Professor, The Cancer Institute of New Jersey and ECOG Genitourinary Cancer Chair
 - Two fully accrued ECOG clinical trials of prostate cancer patients with biochemical failure treated with vaccine.
- 11. Philip Kantoff, Director, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute

- Multicenter phase II and definitive multicenter phase III trial of PSA-TRICOM in patients with minimally symptomatic metastatic CRPC.
- 12. William Oh, Chief, Division of Hematology and Medical Oncology, Tisch Cancer Institute, Mount Sinai Medical Center
 - Initial study of rF-PSA in patients with prostate cancer.
- 13. Fiorella Guadagni, Department of Laboratory Medicine and Advanced Biotechnologies, Istituto di Ricovero e Cura a Carattere Scientifico, San Raffaele, Italy
 - Effect of various anticancer agents on PBMCs.
- 14. Mario Roselli, "Tor Vergata" Clinical Center, University of Rome, Italy
 - Effect of various anticancer agents on PBMCs.
- 15. Robert Kinders, Head, Pharmacodynamics Assay Development Laboratory, SAIC-Frederick/NCI
 - Circulating tumor cell analysis of patients on LTIB studies.
- 16. James Finke, Department of Immunology, Lerner Research Institute, Cleveland Clinic
 - Effect of sunitinib on immune responses in patients with renal cancer.

Industry

- 1. Therion Biologics
 - Trial design for our completed PSA-TRICOM phase II multicenter clinical trial.
- 2. Bavarian Nordic ImmunoTherapeutics
 - Trial design for our proposed PSA-TRICOM phase III multicenter clinical trial.
- 3. GlobeImmune
 - Trial design for CEA- and ras-containing yeast clinical studies.
- 4. Onyvax
 - Trial design for OnyP-1 and OnyP-2 clinical studies.
- 5. BMS/Medarex
 - Trial design for ongoing ipilimumab phase III clinical trial in prostate cancer.
- 6. EMD Serono
 - Trial design for proposed NHS-IL-12 and Stimuvax clinical studies.
- 7. CellGenesis
 - Trial design for proposed GVAX plus radiation clinical trial.
- 8. Cytogen (now EUSA Pharma)
 - Trial design for my ongoing Quadramet with vaccine study (resulted in an agreement to provide free Quadramet for the study valued at approximately \$500,000).

Basic Science

Conducting research in the Laboratory of Tumor Immunology and Biology, Center for Cancer Research, National Cancer Institute, with Dr. Al Tsang, July 1999 to present.

Grant

DOD PC010488 Grant for "A Randomized Phase II Study of a PSA-Based Vaccine in Patients with Localized Prostate Cancer Receiving Standard Radiotherapy." Funded 2002-2004.

EDUCATIONAL ACTIVITIES

Editorial Board Member

Molecular Cancer Therapeutics (an AACR Journal) Emerging Cancer Therapeutics Update on Cancer Therapeutics Prostate Cancer

Invited Guest Editor

Journal of Biomedicine and Biotechnology for a special issue on immune monitoring for cancer vaccines.

Drug Discovery Today: Technologies for a special issue on Prostate Cancer. *Emerging Cancer Therapeutics* for a special issue on Prostate Cancer.

Peer Reviews

Reviewed manuscripts for the following journals: Annals of Internal Medicine, Anti-Cancer Drugs, Blood, British Journal of Urology, Cancer, Cancer Immunology Immunotherapy, Cancer Management and Research, Cancer Research, Clinical Cancer Research, Clinical Evidence, Clinical Medicine: Therapeutics, Current Opinions in Molecular Therapeutics, Emerging Therapeutic Targets, Expert Opinion, Expert Opinion on Biologic Therapy, Expert Opinion On Investigational Drugs, Expert Opinion on Pharmacotherapy, Expert Review of Anticancer Therapy, Expert Review of Vaccines, Human Immunology, Immunotherapy, International Journal of Cancer, Journal of Alternative and Complementary Medicine, Journal of Clinical Oncology, Journal of Dental Research, Journal of Immunotherapy, Journal of Molecular Medicine, Journal of the National Cancer Institute, Journal of Translational Medicine, Lancet, Medicinal Research Reviews, Nature Clinical Practice Urology, Nature Medicine, Neoplasia, New England Journal of Medicine, PNAS, Prostate Cancer and Prostatic Diseases, The Oncologist, and Vaccine.

Teaching

2001: Taught "Cancer Chemotherapy" to medical students, Department of Pharmacology, Uniformed Services University of the Health Sciences, Bethesda, MD.

July 2001: Panelist, NIH Office of Education sponsored workshop for summer students, "How to Become a Member of the Next Generation of Biomedical Scientists."

September 2001: Panelist, National Naval Medical Center televised panel discussion on prostate cancer issues and treatment.

2001 to 2008: National Naval Medical Center inpatient attending 2-4 weeks/year.

2001 to present: NCI Clinical Center inpatient attending 4 weeks/year.

2001 to present: National Naval Medical Center precept medical oncology fellows in clinic 1 day/week or since 2004 Walter Reed Army Medical Center, Center for Prostate Disease Research, precept medical oncology fellows and urology residents in clinic 1 day/week (alternate weeks with NNMC).

2001 to present: Precept medical oncology fellows, NCI Prostate Cancer Clinic, 1 day/week.

2002: Wrote questions for the American Board of Internal Medicine Board Certification Examination.

2004 to 2005: Medical Oncology Attending Physician for TASC (Take a Scientist to the Clinic) Program, National Institutes of Health.

2004 to 2007: Medical oncology fellows biannual lectures, "Androgen-deprivation therapy and staging for patients with prostate cancer."

November 2005: Invited faculty representing medical oncology, 3rd Annual Clinical Investigator Student Trainee Forum, hosted by NIH Clinical Center.

2005 to present: Faculty Member for the Cancer: Pathophysiology, Current Therapies, Clinical Trials, and Drug Development course sponsored by Pharmaceutical Education and Research Institute (PERI), Georgetown University Conference Center, Washington, DC.

2006 to 2009: On committee for developing the standardized medical oncology fellowship in-service training examination in collaboration with ASCO and NBME. Developed all genitourinary cancer questions as well as several other categories for the 2008, 2009 and 2010 tests and was one of 3 finalizing the 2009 test.

2006 to present: Medical oncology fellows lectures, "Immunotherapy for prostate cancer."

2007 to present: Medical oncology attending in charge and discussant, NCI Multi-disciplinary Prostate Cancer Clinic, 1 day every other week.

September 2008: "Prostate cancer for the internist." Lecture to the National Naval Medical Center Internal Medicine Residency program, National Naval Medical Center, Bethesda, MD.

2010: Mentor for the Prostate Cancer Foundation Young Investigator awardees with an interest in immunotherapy (n = 6) at the 17^{th} annual Prostate Cancer Foundation meeting, Washington, DC.

2011-present: "Ethics in the conduct of research: how it applies to you." Introduction to the Principles and Practice of Clinical Research course. NIH, Bethesda, MD.

2011-present: "Immunology Overview." sponsored by Pharmaceutical Education and Research Institute (PERI), Arlington, VA.

Mentoring

Associate Clinical Investigator Mentoring committees

- Ravi Madan, Associate Clinical Investigator
- Andrea Apolo, Associate Clinical Investigator

Medical Oncology Fellows

(Bold = publications with mentee; underlined = clinical trial planned or open with mentee; italics = current position)

Primary Mentor

Nushin Todd Medical Officer at FDA

Ravi Madan Assistant Clinical Investigator at CCR

- Recipient of 2 ASCO Merit Awards including an oral presentation of our work at ASCO
- Recipient of a CCR Assistant Clinical Investigator position

<u>Mahsa Mohebtash</u> Medical Oncologist at Union Memorial Hospital Cancer Center, Baltimore, MD

• Recipient of 2 ASCO Merit Awards of our work

Robert Lechleider Director Oncology, Clinical Development, MedImmune

Marijo Bilusic

Christopher Heery

Joseph Kim

Secondary Mentor

Edwin Posadas Head, Prostate Cancer Clinical Program, Cedars-Sinai Medical Center

Nima Sharifi Assistant Professor at U.T. Southwestern

Shenhong Wu Assistant Professor at SUNY Stony Brook

Jeanny Aragon-Ching Assistant Professor at George Washington U.

Yang-min Ning Medical Officer at FDA

Paul Kluetz Medical Officer at FDA

Avi Retter Semi-academic Private Practice

Bob Behrens Private Practice

Joyson Karakunnel Attending Physician, National Naval Medical Center.

Marc Theoret Medical Officer at FDA

Wenhui Zhu Case Western Reserve University affiliated medical oncologist

David Adelberg

Residents/Medical Students

(Parentheses = position when mentored; italics = current position)

Primary Mentor

Danielle Townsley (Internal Medicine Resident at George Washington University) NCI/NHLBI Hematology Oncology Fellow

Jackie Celestin (Internal Medicine Resident) *Gastroenterology Fellow (clinical nutrition fellowship)*

Christopher Tarassoff (Summer Student for 2 summers, pre-med) *Medical Student at Robert Wood Johnson School of Medicine*.

Secondary Mentor

<u>Jean-Baptiste Latouff</u> (Urologic Oncology Fellow) *Research Clinician and Urologic Oncologist, University of Montreal*

Mitchell Kamrava (Radiation Oncology Resident) Radiation Oncology Resident Alex Gelbard (Howard Hughes Scholar, Medical Student) Medical Student Jarret Feldman (Medical Student) Medical Student

Other Professionals (Primary Mentor Only)

(Parentheses = position when mentored; italics = current position)

Lisa Skarupa (Research Nurse) Medical Officer at FDA

Anne Bastian (Research Nurse) Retired

<u>Laura Novik</u> (Research Nurse) Senior Research Nurse Specialist, Vaccine Research Center, NIAID

Oksook Heath (Research Nurse) Retired

<u>Jackie Jones</u> (Research Nurse) NIH Clinical Center Research Nurse

<u>Steve Morin</u> (Research Nurse) *Nurse Specialist, Health Resources and Services Administration, DHHS*

Sharon Thomas (Clinical Trials Specialist) Regulatory Project Manager, FDA

Jen Marte (Data Manager II) Completed MPH at Johns Hopkins University; *Clinical Research Coordinator at NCI*

Natasha Brunson (Data Manager I) *Data Manager II with Pediatric Oncology Branch* Ghazal Rahmanpanah (Summer Student, high school) *Executive Assistant, Council for Logistics Research, Inc.*

Volunteer Work

1. May 1, 2001, "Prostate cancer and clinical trials at the National Cancer Institute." Lecture to the Andrews Air Force Base Prostate Cancer Support Group.

- 2. October 26, 2001, "Treatment of advanced prostate cancer." Prostate Cancer Support Group sponsored by National Naval Medical Center and the American Cancer Society, National Naval Medical Center.
- 3. March 29, 2002, "Clinical trials for prostate cancer at the National Cancer Institute." Prostate Cancer Support Group sponsored by National Naval Medical Center and the American Cancer Society, National Naval Medical Center.
- 4. April 26, 2002, "Medical School for Junior High." Discussion and role-playing for 7th and 8th graders. John Nevins Andrews Elementary School, Takoma Park, MD.
- 5. May 14, 2002, "Prostate cancer vaccines at the NCI." Southern Maryland Prostate Support Group.
- 6. May 24, 2002, "Immunology for 7th Graders." Discussion and role-playing in immunology for 7th graders. Sligo Adventist Elementary School, Takoma Park, MD.
- 7. May 24, 2002, "Immunology for 8th Graders." Discussion and role-playing in immunology for 8th graders. Sligo Adventist Elementary School, Takoma Park, MD.
- 8. February 28, 2003, "Osteoporosis and prostate cancer." Prostate Cancer Support Group sponsored by National Naval Medical Center and the American Cancer Society, National Naval Medical Center.
- 9. April 15, 2003, Judge, 8th grade (individual) and 6th-8th grade (overall), Sligo Adventist School Science Fair.
- 10. July 1, 2003, "Osteoporosis and prostate cancer." Prostate Cancer Support Group sponsored by the American Cancer Society, Winchester Medical Center, Winchester, VA.
- 11. September 9, 2003, "Prostate cancer clinical trials at the NCI." Lecture for the Anne Arundel Medical Center Prostate Cancer Support Group, Annapolis, MD.
- 12. March 24, 2004, "Prostate cancer clinical trials at the NCI." Lecture for the Man-to-Man Prostate Cancer Support Group, Regional Cancer Therapy Center, Frederick, MD.
- 13. March 19, 2005, "Vaccines for prostate cancer." Lecture to the Westminster chapter of US Too, a prostate cancer support group in Lake Ridge, VA.
- 14. March 23, 2005, "Clinical trials at the NCI in prostate cancer." Lecture to the Man-to-Man Prostate Cancer Support Group, Frederick, MD.
- 15. August 3, 2005, "Vaccines for prostate cancer." Lecture to the Walter Reed Army Medical Center chapter of US Too, a prostate cancer support group in Washington, DC.

- 16. November 12, 2005, "Vaccines for prostate cancer." Lecture to the George Washington University chapter of US Too, a prostate cancer support group in Washington, DC.
- 17. September 22, 2007, "Vaccines and prostate cancer." Lecture to the Westminster chapter of US Too, a prostate cancer support group in Lake Ridge, VA.
- 18. September 26, 2007, "Prostate cancer: what every man (or woman with a man in her life) should know." Lecture to the parishioners of Sligo Seventh-day Adventist Church, Takoma Park, MD.
- 19. May 5, 2008, "Prostate cancer clinical trials at the NCI." Lecture for the Anne Arundel Medical Center Prostate Cancer Support Group, Annapolis, MD.
- 20. September 11, 2008, "Prostate cancer clinical studies: hope for the future." Lecture for the FACES, Inc. 4th Annual Men's Health Forum, an educational meeting for patients and families. Martin Luther King Jr. Memorial Library, Washington, DC.
- 21. September 18, 2010, "Immunotherapy for prostate cancer: training your immune system to fight cancer!" Lecture to the Westminster-Potomac Hospital chapter of US Too, a prostate cancer support group, Lake Ridge, VA.
- 22. November 3, 2010, "Immunotherapy for prostate cancer: training your immune system to fight cancer!" Lecture to the Walter Reed Army Medical Center chapter of US Too, a prostate cancer support group, Washington, DC.

Community Outreach

May 2002 to present, Elder, Sligo Seventh-day Adventist Church.

January 2005 to present, Sabbath School Teacher, ages 3-6, Sligo Seventh-day Adventist Church.

June 2005 to present, Chair, Stewardship Committee, Sligo Seventh-day Adventist Church.

June 2005 to present, Member, Finance Committee, Sligo Seventh-day Adventist Church.

June 2005 to present, Member, Church Board, Sligo Seventh-day Adventist Church.

2006 to 2010, NCI Liaison, FACES project, a non-profit organization dedicated to education/screening for prostate cancer directed at men of color in the greater DC area.

ORGANIZATIONAL ACTIVITIES

Committees/Boards

NIH Committees

- Clinical Co-chair, NIH Fellows Committee (2000–2001)
 - o Chair, Distinguished Clinical Teachers Award Subcommittee (2000–2001)
 - o Mentoring Subcommittee (2000–2002)
 - o Publicity Subcommittee (2000–2001)
- Committee on Scientific Conduct and Ethics (2003–present)
 - o **Chair**, NIH Committee on Scientific Conduct and Ethics subcommittee for a scientific misconduct inquiry (NIH-09-08).

Center for Cancer Research (CCR) Committees

- Gastrointestinal Malignancies Faculty Steering Committee (2003–2006)
- CCR Grand Rounds Planning Committee (2006–2008; 2010–2011)
- NCI IRB (frequently served as **chair**) (2007–2009)
 - o NCI IRB Serious Adverse Events Subcommittee (2007–2009)
- Informed Consent Template Committee (2008)
- CCR Clinical Review Panel (2008–2011)
- Chair, Evaluation and Metrics Working Group (2008–2009)
- Protocol Scientific Review Working Group (2008–2009)
- Member, Genitourinary Cancer Center of Excellence Steering Committee (2009-present)
- Chair, CCR Safety Monitoring Committee (2010-present)
- Member, Scientific Review Committee, Urologic Oncology Branch
- Member, Scientific Review Committee, Radiation Oncology Branch/Neuro-Oncology Branch
- Member, Clinical Tenure-Track Principal Investigator Search Committee, Urologic Oncology Branch, (2010 to present).

Clinical Center Committees

- iMedRIS Clinical Trials Implementation Committee (2006)
- Patient Care Unit Partners Committee (3NE and 3SE) (2004–2009)
- Biomedical Translational Research Information System (BTRIS) PI User Group (2009-2010).

Laboratory of Tumor Immunology and Biology (LTIB) Committees

- Member, Clinical Trials Steering Committee, (2005 to present)
- Member, Research Tenure-Track Principal Investigator Search Committee, (2009 to present)

Medical Oncology Branch (MOB) Committees

- Fellowship Curriculum Committee (2001–2008)
- **Deputy Chair**, MOB Scientific Review Committee (2004–present)
- Chair, MOB Website Committee (2006–present)

Extramural/National Committees

- Chair, first NCI working group convened to design 3 prospective, randomized controlled trials in prostate cancer patients using PSA-TRICOM vaccines (2002)
- Immunology Devices Panel, Medical Devices Advisory Committee, Center for Devices and Radiological Health, FDA (2004–2008)
- Founding Member, Prostate Cancer Immunotherapy Group (PIGs), (2007-present).
- Founding Member, ASCO Medical Oncology In-Training Exam Test Materials Development Committee (2007–2010)
- NCI Liaison to FACES (prostate cancer patient support and education nonprofit) (2007–2010)
- Founding Member, Prostate Cancer Working Group (CTEP committee) (2009–present)
- Consultant, Reproductive Health Drugs Advisory Committee (2009)

Leadership Activities

- "Designing a phase II study in advanced prostate cancer." Facilitator, clinical trial breakout session, 4th Annual Innovators in Urology Meeting, Vancouver, BC, September 24, 2004.
- "Cancer therapies." Discussion moderator, SynCure Cancer Research Foundation's Update 2005: Cancer Research and Treatment, Tallahassee, FL, April 9, 2005.
- Panelist, Immune Assay Harmonization Panel, Cancer Immunotherapy Consortium, March 19, 2010.
- Chair, NCI Gastrointestinal Malignancy Retreat, Bethesda, MD. October 12, 2010.
- Moderator, Direct-to-Patient Trials Round Table at the Accelerating Proof of Concept meeting, Philadelphia, PA. October 6, 2010.
- Advisor, Pfizer Vaccine Group's Prostate Cancer Immunotherapy Think Tank meeting discussing known clinical data and potential clinical trials strategies, La Jolla, CA. November 8, 2011.
- Chair, Cancer Vaccines & Immunotherapeutics at the Strategies for Clinical Oncology Drug Development meeting, San Francisco, CA. Scheduled for February 23, 2011.
- Moderator, Picking Perfect Patients Breakout session at the Strategies for Clinical Oncology Drug Development Track, Molecular Medicine Tri-Con, San Francisco, CA. February 23, 2011.
- Chair, Oncology Clinical Trials at the Strategies for Clinical Oncology Drug Development Track, Molecular Medicine Tri-Con, San Francisco, CA. February 25, 2011.
- Chair, Clinical Science Symposium, "Personalized Medicine", at the American Society of Clinical Oncology annual meeting, Chicago, IL. Scheduled for June 3, 2011.
- **Co-chair**, Prostate Cancer Vaccines session at the Society for Immunotherapy of Cancer (SITC) annual meeting, Bethesda, MD. Scheduled for November 2011.

Consultant/Reviewer

2001, Chief Judge, Tumor Immunology and Therapy Study Section, Fellows Award for Research Excellence, NIH.

2001-2003, Consultant, Prostate Clinical Advisory Board, Therion Biologics Corporation, Boston, MA.

2002-2004, Consultant and Member, Lecture Bureau for Prostate Cancer, AstraZeneca LP.

2003, Scientist Reviewer, Congressionally Directed Medical Research Programs, Prostate Cancer Research Program, Immunological Sciences.

January 2004, Author, requested narrative on prostate cancer research for the NCI Office of Budget and Financial Management, to be used in the congressional appropriations process.

2004, Scientific Reviewer, Advanced Technology Program, National Institute of Standards and Technology, U.S. Department of Commerce.

2004-2008, Consultant, Immunology Devices Panel, Medical Devices Advisory Committee, Center for Devices and Radiological Health, Food and Drug Administration.

2004-present, Scientific Reviewer of Clinical Trials, Medical Oncology Branch, Center for Cancer Research, National Cancer Institute.

2006, Scientific Reviewer of the Avon-NCI Progress for Patients Awards, Early Phase Clinical Interventions in Breast Cancer.

2007, Reviewer for the National Institute of Allergy, Immunology and Infectious Diseases (NIAID), National Institutes of Health for the Vaccine and Treatment Evaluation Units.

2007, Scientific Reviewer for the START program of the Austrian Science Fund.

2007, Scientific Reviewer for the Veteran's Administration's Clinical Trial Development Award.

2008, Invited to be a Scientist Reviewer, Congressionally Directed Medical Research Programs, Prostate Cancer Research Program, Idea Awards.

January 2009, Scientific Reviewer: Reviewed a grant for the Ulster Cancer Foundation.

March 2009, Invited to be a Scientist Reviewer, Congressionally Directed Medical Research Programs, Prostate Cancer Research Program, PRE-Clinical and Experimental Therapeutics D (PRE-CET-D).

June 8-9, 2009, Ad Hoc Member, Cancer Immunopathology and Immunotherapy (CII) study section meeting.

June 9, 2009, Ad Hoc Member, Cancer Immunotherapy ARRA CR study section meeting.

October 2009, Reviewed a randomized Phase III trial concept as an immunotherapy clinical trials expert for the Cancer Therapy Evaluation Program (CTEP) Breast Cancer Steering Committee.

2009, Scientist Reviewer, Immunology (IMM) peer review panel of the Prostate Cancer Research Program (PCRP) for the Department of Defense (DoD) Congressionally Directed Medical Research Programs (CDMRP).

Spring 2010, Ad Hoc Member, Recombinant DNA Advisory Committee (RAC).

October 18, 2010, Reviewer, Operational Review of NIH Clinical Center's Radiology and Imaging Sciences Department.

2010-2011, Member, Prostate Cancer Foundation Research Awards Standing Review Committee for Immunotherapy.

February 7, 2011, Reviewer, Cancer Immunotherapy Trials Network for site selection of initial member sites.

Memberships/Societies

American Society of Clinical Oncology
American Association for Cancer Research
International Society for Biological Therapy of Cancer
American Society for Therapeutic Radiology and Oncology
Affiliate, American Urological Association
American College of Physicians
European Society of Cancer Immunology and Immunotherapy
Immunology Faculty, NCI, 2002 to present
Medical Reserves Corps, 2001 to present
Genitourinary Malignancies Faculty, NCI, 2001 to present
Vaccine Working Group, NCI, NIH, 2001 to present
Immunology Interest Group, NIH, 2001 to present

RECOGNITION

Honors

1985 Outstanding Freshman Award, "In Recognition of Academic Excellence," Southern Adventist University
1985 CRC Press Freshman Chemistry Achievement Award
1987 Magna Cum Laude, Southern Adventist University

- 1987 Southern Scholar, Southern Adventist University
- 1988 Medical Scientist Training Program, Loma Linda University
- 1993 Selma Andrews Award, Loma Linda University
- 1996 Resident Achievement Award, "For Excellence in Internal Medicine," Emory University
- 1997 Offered position as Chief Resident of Internal Medicine, Emory University
- 2000 AACR/ASCO Methods in Clinical Research awardee
- 2001 Senior Fellowship Training Award, NCI, NIH
- 2001 Merit Award, American Society of Clinical Oncology
- 2001 Physicians Recognition Award, American Medical Association
- 2003 NCI Group Merit Award, "For Major Contributions to the Field of Cancer Immunotherapy"
- 2004 NIH Fellows Committee Award, "For Outstanding Contributions to the Training of Clinical Fellows and the Advancement of Clinical Research"
- 2005 National Cancer Institute Technology Transfer Award
- 2006 Mary Crowley Medical Research Center Excellence Award
- 2006 Federal Technology Transfer Award
- 2007 Distinguished Clinical Teacher Award nominee, NIH Fellows Committee
- 2007 Federal Technology Transfer Award
- 2008 US FDA Advisory Committee Service Award "In recognition of distinguished service, Immunology Devices Panel, March 2004-February 2008"
- 2008 NCI Director's "10 year length of service award"
- 2008 Federal Technology Transfer Award
- 2009 NIH Group Merit Award "For achievements in the field of therapeutic cancer vaccines, from vaccine design to science-driven clinical studies, as an outstanding translational program."

Media Interviews

- 1. "Prostate Cancer," member of panel of experts discussing issues relating to prostate cancer for the National Naval Medical Center television series.
- 2. Ellen Maurer, "Choices: Treatments for Prostate Cancer," *The Journal*, National Naval Medical Center official newspaper, September 6, 2001, Vol. 13, No. 35, p. 3.
- 3. Brian Reid, "AACR: New Vaccine Plus Radiotherapy Boosts T-cell Response in Prostate-Cancer Patients," July 15, 2003, DGDispatch.
- 4. Rob Stein, "Treatment for Prostate Cancer Shows Promise: Vaccine in Study Pushed Immune System to Attack Tumors, Allowing Patients to Live Longer," *The Washington Post*, February 17, 2005, p. A2.
- 5. Bryan Hyde, "The Bryan Hyde Show," live interview on reports of survival data from the Dendreon study, KDXU-AM, Saint George, UT, March 4, 2005.

- 6. NIH Radio News Service, interview on a report in *Clinical Cancer Research* on the combination of vaccine and radiation therapy for patients with localized or locally advanced prostate cancer, Bethesda, MD, May 9, 2005.
- 7. "Radiation/Cancer-Vaccine Combination Therapy May Benefit Patients with Prostate Cancer," NIH Radio Audio Reports. Available at: http://www.nih.gov/news/radio/jun2005/06182005combination.htm. Posted June 18, 2005.
- 8. "Fewer CT Scans Needed after Surgery for Low-Risk, Early-Stage Testicular Cancer," NCI Clinical Trial Results. Available at: http://www.cancer.gov/clinicaltrials/results/testicular-scans0606. Posted: June 28, 2006.
- 9. "Vaccine Combined with EBRT Effective for Patients with Localized Prostate Cancer," *Nature Clinical Practice Urology*, July 2005;2(7):313.
- 10. "Chemo for Early-Stage Testicular Cancer More Effective than Lymph-Node Dissection in Preventing Relapse," NCI Clinical Trial Results. Available at: http://www.cancer.gov/clinicaltrials/results/testicular0706. Posted: July 12, 2006.
- 11. "Featured Clinical Trial: Prostate Cancer Vaccine Trial," NCI Cancer Bulletin.

 Available at:
 http://www.cancer.gov/ncicancerbulletin/NCI_Cancer_Bulletin_100306/page7?cb_emaile=1. Posted: October 3, 2006.
- 12. "A New Approach to an Old Scourge," Found in Translation: The Life Science Newsletter on Translational Medicine. Available at: http://www.foundintranslation.org/article2.html. Posted January 2007.
- 13. March 7, 2007. Interviewed at NIH for Israeli television documentary to be aired in primetime on one of the largest commercial TV stations in Israel.
- 14. "Alternative Vaccine Strategy Shows Promise In Prostate Cancer Patients" NCI Press release http://www.cancer.gov/newscenter/pressreleases/MetronomicIL-2Gulley/print?page=&keyword Posted August 15, 2008.
- 15. "Alternative Vaccine Strategy Shows Promise In Prostate Cancer Patients" <u>ScienceDaily</u> (Aug. 25, 2008) http://www.sciencedaily.com/releases/2008/08/080824201235.htm
- 16. Interviewed by host Maurice Pickard MD for ReachMD, <u>Radio XM 157</u> on Prostate Cancer Vaccines. Interview aired September, 2008 http://www.reachmd.com/xmradioguest.aspx?pid=30094
- 17. Interviewed by Liz Sabo for <u>USA Today</u> for their April 14, 2009 report entitled "Vaccine shows promise for prostate cancer treatment, company says." http://www.usatoday.com/news/health/2009-04-14-prostate-cancer-vaccine N.htm

- 18. Interviewed by Liz Sabo for <u>USA Today</u> for their April 28, 2009 report entitled "Provenge vaccine prolongs life in prostate cancer patients." http://www.usatoday.com/news/health/2009-04-28-provenge-prostate_N.htm
- 19. Interviewed by Heidi Ledford for <u>Nature News</u> for their April 29, 2009 report entitled "Controversial vaccine fights prostate cancer." http://www.nature.com/news/2009/090429/full/news.2009.414.html
- 20. Interviewed by Carmen Phillips for the NCI Cancer Bulletin for their June 2, 2009 Special Report. http://www.cancer.gov/ncicancerbulletin/060209/page4
- 21. Interviewed by Carmen Phillips for the NCI Cancer Bulletin for their September 8, 2009 report on Denosumab: "Monoclonal Antibody Keeps Bones Strong during Prostate Cancer Treatment." http://www.cancer.gov/ncicancerbulletin/090809/page3#c
- 22. Interviewed by Katy Human for *Cure* on November 13, 2009 for her report on therapeutic cancer vaccines entitled "Getting Personal" which was published in the Spring Issue 2010 (Volume 9, Number 1, pages 34-40).
- 23. Interviewed by Michael Becker MD March 12, 2010 for "Cancer Vaccine Therapies: Failures and Future Opportunities" a 153 page white paper on therapeutic vaccines. ©2010, Becker Partners LLC.
- 24. Interviewed by Mark Roth April 2, 2010 for an article on MUC-1 containing vaccines for the Pittsburgh Post-Gazette for the April 7, 2010 article entitled "Cancer vaccines may be on the verge of wider use. http://www.post-gazette.com/pg/10097/1048313-114.stm
- 25. Interviewed by Carmen Phillips on April 28, 2010 for an article entitled "FDA Approves First Therapeutic Cancer Vaccine" with a side bar on PSA-TRICOM entitled "Another Vaccine, a Different Approach" for the May 4, 2010 edition of the *NCI Cancer Bulletin*. http://www.cancer.gov/ncicancerbulletin/050410/page2
- 26. Interviewed by Liz Szabo of *USA Today* on April 29, 2010 for an article entitled "FDA approves prostate cancer vaccine" in the April 30 edition of *USA Today*. http://www.usatoday.com/news/health/2010-04-30-prostatevaccine30_ST_N.htm?csp=34
- 27. Interviewed by Rob Stein of the *Washington Post* on April 29, 2010 for an article entitled "FDA approves prostate cancer 'vaccine' from Dendreon called Provenge" in the April 30 edition of the *Washington Post*. http://www.washingtonpost.com/wp-dyn/content/article/2010/04/29/AR2010042902684.html?hpid=topnews
- 28. Interviewed by Michael Flanagan, Senior Writer of BioCentury Publications on April 29, 2010 for his article entitled "What is next for the cancer immunotherapy space?"
- 29. Interviewed by Mark Cantrell on May 28, 2010 who was commissioned by *Baylor Innovations* to write an article on Prostate Cancer Vaccines.

- 30. Interviewed by Edward R. Winstead for his article entitled "Experimental Drug Improves Survival in Advanced Melanoma" on Ipilimumab published in the June 15, 2010 edition of the *NCI Cancer Bulletin*. http://www.cancer.gov/ncicancerbulletin/061510/page2
- 31. Interviewed by Betsy Q. Cliff of *The Bulletin* from Bend Oregon for an article on therapeutic vaccines for lung cancer.
- 32. Interviewed by Elizabeth Anderson for Columbia Union *Visitor Magazine* for an article on "Cool Jobs" in the DC area on June 18, 2010.
- 33. Interviewed by Carina Storrs for *Popular Science* for an article about therapeutic vaccines for prostate cancer on June 23, 2010.
- 34. Interviewed by Elizabeth Krutoholow Editor of *Pharmawire* for an article on Denosumab about findings with this drug in prostate cancer on June 30, 2010.
- 35. Interviewed by Alan Bavley of the *Kansas City Star* for his article on therapeutic vaccines for cancer on August 3, 2010.
- 36. Participated in "panel of experts" for "BioCentury This Week" TV, a production of CBS/WUSA channel 9, Washington, DC, on the topic of Medicare uncertainties re Provenge, and what clinicians expect to accomplish in "real life" with Provenge. Sunday, October 14, 2010.
- 37. Interviewed for the article entitled "Therapeutic Synergies in the Fight Against Cancer" published in Volume 4, number 1 of the CCR Connections magazine, 2010.
- 38. Interviewed by Liz Szabo of *USA Today* on January 31, 2011 for an embargoed *Nature* research letter on a four gene signature predicting biochemical recurrence and lethal outcome in patients with prostate cancer.
- 39. Interviewed by Kelly Chi on February 1, 2011 for a feature for *NatureJobs* (http://www.nature.com/naturejobs/news/index.html) about cancer vaccine job opportunities.
- 40. Interviewed by Laura Hambleton of the Washington Post for a feature on clinical trials at the NIH to be published May 24, 2011.

Invited Presentations

Institutions and Universities

1. "Immunotherapy of prostate cancer." Grand Rounds (CME credit given), Suburban Hospital, Bethesda, MD, January 19, 2001.

- 2. "Immunotherapy of prostate cancer." Grand Rounds (CME credit given), Doctors Community Hospital, Prince George's County, MD, May 31, 2001.
- 3. "A PSA-based vaccine in a randomized phase II study of patients with localized prostate cancer receiving standard radiotherapy." Oral presentation to the Center for Cancer Research Postdoctoral and Trainees Assembly Retreat, June 12-13, 2001.
- 4. "Immunotherapy of prostate cancer." Winship Cancer Institute Director's Seminar, Emory University, Atlanta, GA, June 28, 2001.
- 5. "Cancer vaccines: a translational research initiative." National Institutes of Health Bench to Bedside Grand Rounds (CME credit given), January 30, 2002.
- 6. "Vaccines for cancer: what we have learned and where we are going." E.O. Grundset lecture series for the Biology/Allied Health Department, Southern Adventist University, Collegedale, TN, March 21, 2002.
- 7. "Vaccine program at the NCI." Lecture to NCI medical oncology fellows, National Naval Medical Center, July 5, 2002.
- 8. "Genitourinary cancers." Lecture to medical oncology fellows (NCI and Walter Reed Army Medical Center), National Naval Medical Center, August 8, 2002.
- 9. "Poxviral prostate cancer vaccines." Lecture to NCI medical oncology fellows, National Naval Medical Center, August 23, 2002.
- 10. "Immunology and tumor immunotherapy." Lecture given to clinical researchers at the National Naval Medical Center, February 25, 2003.
- 11. "Development of prostate cancer vaccines." Lecture given to the Genitourinary Malignancies Faculty, National Cancer Institute, Warren Grant Magnuson Clinical Center, May 6, 2003.
- 12. "Development of prostate cancer vaccines." Lecture given to the basic science faculty and staff at the Center for Molecular Biology and Gene Therapy, Loma Linda University, Loma Linda, CA, August 7, 2003.
- 13. "Vaccines for cancer." Lecture given to the senior dental students, faculty and staff at the School of Dentistry, Loma Linda University, Loma Linda, CA, August 8, 2003.
- 14. "Development of prostate cancer vaccines." Lecture at Medical Grand Rounds, University of Nebraska School of Medicine, September 29, 2003.
- 15. "Prostate cancer clinical trials at the NCI." Lecture for the Suburban Hospital Prostate Cancer Support Group, Bethesda, MD, November 17, 2003.

- 16. "Osteoporosis and prostate cancer." CME lecture sponsored by Doctors Community Hospital, Bethesda, MD, December 15, 2003.
- 17. "Vaccine-related clinical trials." Lecture to the Genitourinary Malignancies Faculty at the National Cancer Institute, Bethesda, MD, January 6, 2004.
- 18. "Prostate cancer and bone disease." CME lecture for Walter Reed Army Medical Center Medical Oncology Fellows and Staff, Washington, DC, February 20, 2004.
- 19. "Vaccine and radiation for localized prostate cancer." Lecture for the Spring 2004 NCI CTEP Early Drug Development Meeting, Bethesda, MD, February 25, 2004.
- 20. "Vaccine therapies: prostate cancer." CME lecture sponsored by Doctors Community Hospital, Metropolitan Ambulatory Urologic Institute, and Genitourinary Malignancies Faculty, Bethesda, MD, March 13, 2004.
- 21. "Development of prostate cancer vaccines." Oral presentation to the Immunology Faculty, Center for Cancer Research, NCI, Bethesda, MD, April 20, 2004.
- 22. "Low-dose IL-2 for tumor immunotherapy." One of 3 invited speakers (with Dr. Kendall Smith and Dr. Steven Rosenberg), Immunology Faculty, Center for Cancer Research, NCI, Bethesda, MD, May 4, 2004.
- 23. "How to succeed as a Principal Investigator at the NIH." Presentation to tenure-track NIH investigators, Gettysburg, PA, May 18, 2004.
- 24. "Osteoporosis and prostate cancer." Lecture sponsored by AstraZeneca, Washington, DC, July 28, 2004.
- 25. "When to use androgen-deprivation therapy following definitive local therapy." Lecture to medical students and urology residents, Walter Reed Army Medical Center, March 11, 2005.
- 26. "New generation cancer drugs and immunotherapy." Lecture at SynCure Cancer Research Foundation's Update 2005: Cancer Research and Treatment, Tallahassee, FL, April 9, 2005.
- 27. "Pox-viral vaccines for cancer therapy: a translational journey." Plenary session oral presentation to the Breast and Gynecologic Malignancy Faculty of the National Cancer Institute, Flintstone, MD, July 21, 2005.
- 28. "Prostate cancer." Lecture to Internal Medicine Residents at the National Naval Medical Center, Bethesda, MD, August 11, 2005.
- 29. "A phase II study of a PSA-TRICOM vaccine, and the role of GM-CSF, in patients with metastatic androgen-insensitive prostate cancer." Presentation to the Translational

- Immunology Related to Cancer Conference, Masur Auditorium, NIH Clinical Center, Bethesda, MD, September 22-23, 2005.
- 30. "A phase I feasibility study of an intraprostatic PSA-based vaccine in prostate cancer patients with local failure following radiotherapy or clinical progression on androgen-deprivation therapy in the absence of local definitive therapy." Presentation to the Surgery Branch of the National Cancer Institute at the NIH Clinical Center, Bethesda, MD, October 24, 2005.
- 31. "Recombinant cancer vaccines: translational research and combination therapies for patients with solid tumors." CME lecture to the Pediatric Oncology Branch Grand Rounds, NCI, March 9, 2006.
- 32. "Vaccines for cancer treatment: a translational journey from conception to phase III clinical studies." GME Grand Rounds Presentation at West Virginia University, Morgantown, WV, March 24, 2006.
- 33. "Treatment options in metastatic androgen-independent prostate cancer." Lecture to the residents and staff at the Center for Prostate Disease Research, Walter Reed Army Medical Center, Washington, DC, April 7, 2006.
- 34. "Vaccines and prostate cancer." Lecture for the NCI-sponsored Symposium for Practicing Physicians, Natcher Conference Center, NCI, Bethesda, MD, May 6, 2006.
- 35. "Vaccines for prostate cancer: a translational journey from conception to phase III clinical studies." CME Medical Oncology Grand Rounds, University of Chicago, Chicago, IL, August 28, 2006.
- 36. "Treatment options in metastatic androgen-independent prostate cancer." Lecture to residents and staff, Center for Prostate Disease Research, Walter Reed Army Medical Center, Washington, DC, September 1, 2006.
- 37. "The future role of cancer vaccines." Cancer *Care* Cancer Vaccine Telephone Education Workshop, November 15, 2006.
- 38. "Utilizing radiation to alter tumor phenotype: implications for immunotherapy." Lecture to the 2nd International Cancer Vaccine Meeting, Sienna, Italy, December 10, 2006.
- 39. "Prostate cancer clinical update." Lecture as a Faculty Member for the Cancer: Pathophysiology, Current Therapies, Clinical Trials, and Drug Development course sponsored by Pharmaceutical Education and Research Institute (PERI), Georgetown University Conference Center, Washington, DC, April, 2007.
- 40. "Poxviral vaccines for prostate cancer: what we have learned." A state-of-the-art lecture to the Cancer and Leukemia Group B (CALGB) Genitourinary Malignancies Core Committee Annual Meeting, Baltimore, MD, June 23, 2007.

- 41. "Prostate cancer for the internist." Lecture to the National Naval Medical Center Internal Medicine Residency program, National Naval Medical Center, Bethesda, MD, August 9, 2007.
- 42. "Radiation and vaccines: preclinical rationale and clinical results." Lecture to the Radiation Therapy Workshop, Natcher Building, NIH, Bethesda, MD, December 5, 2007.
- 43. "Immunotherapy for prostate cancer: novel approaches and preliminary findings." Lecture to the NCI Vaccine Working Group, NIH, Bethesda, MD, December 11, 2007.
- 44. "Prostate cancer immunotherapy at the NCI: novel approaches and preliminary findings." Grand Rounds lecture to University of Wisconsin Paul P. Carbone Comprehensive Cancer Center, Madison, WI, January 9, 2008.
- 45. "Clinical Immunotherapy Group: clinical program." A lecture to the Medical Oncology Branch, NIH Clinical Center, Bethesda, MD, February 29, 2008.
- 46. "Enhancing immune-mediated anticancer reactivity by costimulation: preclinical data and initial clinical trial results." Lecture to the 9th International Symposium of Biological Therapy of Cancer, co-organized by the Biotherapy Development Association, European Society of Medical Oncology and National Cancer Institute, Munich, Germany, March 13, 2008.
- 47. "Facilitating immunotherapy via radiation therapy." Lecture to the Cancer Therapy Evaluation Program (CTEP), Rockville, MD, April 2, 2008.
- 48. "Prostate cancer immunotherapy at the NCI: novel approaches and preliminary findings." Immunology Seminar Series, Johns Hopkins University Medical Center, Baltimore, MD, April 4, 2008.
- 49. "Cancer immunotherapy: new insights and new frontiers from prostate cancer clinical trials." Lecture to the basic science faculty and staff at the Center for Molecular Biology and Gene Therapy, Loma Linda University, Loma Linda, CA, May 1, 2008.
- 50. "Novel clinical trials in prostate cancer at the NCI." Lecture to the radiation oncology residency program, videoconferenced to the NNMC radiation oncology residency program, NIH Clinical Center, Bethesda, MD, October 1, 2008.
- 51. "Castration-resistant prostate cancer: standard therapies and novel approaches." Medical Oncology Grand Rounds lecture at Walter Reed Army Medical Center, Washington, DC, October 29, 2008.
- 52. "Treatment of advanced prostate cancer." Grand Rounds lecture at George Washington University Department of Urology, George Washington University Medical Center, Washington, DC, December 10, 2008.

- 53. "Castration-resistant prostate cancer: standard therapies and novel approaches." A "State of the Art" lecture at the 56th Annual James C. Kimbrough Urologic Seminar, Capitol Hill Hyatt Regency, Washington, DC, January 15, 2009.
- 54. "On being a doctor: what it means to be a translational researcher." Lecture to the Premedical Club, Southern Adventist University, Collegedale, TN, February 23, 2009.
- 55. "Immunotherapy for prostate cancer: emerging paradigms and combination therapies." Lecture to the Medical Oncology Branch Friday Lecture Series for Senior Staff and Fellows, NIH Clinical Center, Bethesda, MD, March 27, 2009.
- 56. "Immunotherapy for prostate cancer." Lecture to the MOB Medical Oncology Fellows, NIH Clinical Center, Bethesda, MD, March 30, 2009.
- 57. "A multi-center randomized controlled Phase II clinical trial of PSA-TRICOM: final overall survival data." Best of ASCO lecture to CCR investigators and fellows at the Medical Oncology Branch Friday Lecture Series, NIH Clinical Center, Bethesda, MD, June 19, 2009.
- 58. "Development of recombinant vaccines for the therapy of carcinomas." Lecture at Bristol-Myers Squibb in Wallingford, CT, July 14, 2009.
- 59. "Immunotherapy for prostate cancer." Lecture to the Hematology/Oncology Fellows and Staff, Washington Cancer Institute, Washington Hospital Center, Washington, DC, August 10, 2009.
- 60. "PSA-TRICOM: the winding translational pathway from preclinical to phase III." Lecture to Radiation Oncology Branch faculty and staff, NCI, September 30, 2009.
- 61. "Of mice and men: the odyssey of poxviral vector translational studies from preclinical to randomized controlled clinical trials." Lecture for monthly CPDR Research Seminars, Center for Prostate Disease Research (CPDR)/Uniformed Services University of the Health Sciences, Rockville, MD, November 4, 2009.
- 62. "The translational odyssey of poxviral vaccines from preclinical to randomized controlled studies" Lecture at the British Columbia Cancer Agency, Deeley Research Centre's Immunotherapy Seminar Series. Broadcast via video link to the BC Cancer Research Centre, Terry Fox Laboratories, and the Fred Hutchinson Cancer Research Centre, Victoria, BC, November 18, 2009.
- 63. "Kinetics of an immune response: slow and steady wins the race." Lecture to personnel at Dendreon Corporation, Seattle, WA, November 19, 2009.
- 64. "Therapeutic vaccines and tumor volume: does size matter?" Grand Rounds presentation at McGill General Hospital, organized by the Visiting Speakers Program in Oncology

- (VSPO), run jointly between McGill University and Université de Montréal, Montreal, Quebec, December 9, 2009.
- 65. "The translational odyssey of poxviral vaccines from preclinical to randomized controlled studies." Grand Rounds presentation at Notre Dame Hospital, with video link to St. Luke's Hospital, organized by the Visiting Speakers Program in Oncology (VSPO), run jointly between McGill University and Université de Montréal, Montreal, Quebec, December 10, 2009.
- 66. "The translational odyssey of poxviral vaccines from preclinical to randomized controlled studies." Lecture to Radiation Oncology Branch faculty and staff and the Tenure Track Selection Committee, NCI., Bethesda, MD, January 6, 2010.
- 67. "Therapeutic vaccines for prostate cancer: advances in understanding of trial design and patient selection." Lecture at 1st Annual NCI Genitourinary Center of Excellence Meeting, Bethesda, MD, March 12, 2010.
- 68. "Therapeutic vaccines for cancer: finally light at the end of the tunnel." Invited lecture to faculty, staff, and trainees at the National Institute of Immunology, New Delhi, India, April 15, 2010.
- 69. "The translational odyssey of poxviral vaccines: from preclinical to randomized controlled clinical trials." Invited lecture to faculty, staff, and trainees at the Institute of Liver and Biliary Sciences, New Delhi, India, April 19, 2010.
- 70. "Therapeutic vaccines for prostate cancer: advances in understanding of trial design and patient selection." Lecture to Medical Oncology Branch senior staff, fellows, and guests, NIH Clinical Center, Bethesda, MD, May 14, 2010.
- 71. "Therapeutic vaccines: why traditional surrogates of efficacy fail." Webinar hosted by PERI, May 18, 2010.
- 72. "Therapeutic vaccines for prostate cancer: advances in understanding of trial design and patient selection." Lecture at weekly Cancer Conference, George Washington University Hospital, Washington, DC, May 28, 2010.
- 73. "PROSTVAC: a promising new therapeutic vaccine for prostate cancer." Lecture to the Board of the Prostate Cancer Foundation, July 15, 2010.
- 74. "Prostate cancer." Lecture for "A Basic Overview of Current Therapies for New Oncology Researchers," PERI Training Facility, Arlington, VA, July 20, 2010.
- 75. "Combining therapeutic vaccines with traditional oncologic modalities: the next frontier." Invited lecture at the Clinical and Translational Immunology Seminar, M.D. Anderson Comprehensive Cancer Center, Houston, TX, August 25, 2010.

- 76. "PSA-TRICOM: the winding translational pathway from preclinical to phase III and beyond." Invited lecture to the CCR Radiation Oncology Branch Residency Program, with videocast to WRAMC and NNMC radiation oncology residency programs, NIH, Bethesda, MD, September 7, 2010.
- 77. "Expanding the fight against cancer." Invited lecture to Shenandoah Valley Academy High School seniors' Anatomy and Physiology class, New Market, VA, September 17, 2010.
- 78. "PROSTVAC: a promising new therapeutic vaccine for prostate cancer." Invited lecture to the NIH Immunology Interest Group Annual Retreat, Cambridge, MD, September 21, 2010.
- 79. "Design and Development of Recombinant Vaccines for Cancer Therapy." NIH/CCR Grand Rounds. November 30, 2010.
- 80. "Understanding the Promise of Therapeutic Vaccines for Cancer Treatment." Keynote lecture at town hall seminar, EMD Serono, Darmstadt, Germany. December 8, 2010.
- 81. "Thwarting the gain without the pain: Impact of therapeutic vaccines on tumor growth." Urologic Oncology Branch, NIH, Bethesda, MD. January 19, 2011.
- 82. "Ethics in the Conduct of Research How It Applies to You." Introduction to the Principles and Practice of Clinical Research course. NIH, Bethesda, MD. February 1, 2011.
- 83. "Vaccine Combination Therapy: Rationale and Preliminary Data for two Randomized Phase II Studies." Cancer Therapy Evaluation Program (CTEP) Early Drug Development Meeting, NIH, Bethesda, MD. March 14, 2011.
- 84. "NCI-developed prostate cancer vaccine: from laboratory to phase III." Invited lecture to Congressional Staffers. NIH, Bethesda, MD. March 18, 2011.
- 85. "Prostate Cancer: Challenge in mechanism and treatment." A lecture for the Demystifying Medicine lecture series, NIH Bethesda, MD. April 19, 2011.
- 86. "The current and emerging role of immunotherapy in prostate cancer." New Perspectives on Prostate Cancer 2011, sponsored by Washington Adventist Hospital. Pooks Hill Marriott, Bethesda, MD. Scheduled for November 4, 2011.

National and International Meetings

1. "A PSA-based vaccine in a randomized phase II study of patients with localized prostate cancer receiving standard radiotherapy." Oral presentation, 4th Annual Society of Urologic Oncology Meeting, Bethesda, MD, December 6, 2003.

- 2. "A phase II study of PROSTVAC-VF vaccine and the role of GM-CSF in patients (pts) with metastatic androgen-insensitive prostate cancer (AIPC)." Oral presentation, American Society for Clinical Oncology, Orlando, FL, May 16, 2005.
- 3. "A phase II study of PROSTVAC-VF vaccine and the role of GM-CSF in patients with metastatic androgen-insensitive prostate cancer." Oral presentation, 13th International Conference on Gene Therapy of Cancer, Coronado, CA, September 9, 2005.
- 4. "Vaccines for prostate cancer: a translational journey from conception to phase III clinical studies." Oral presentation to the 4th International Cancer Vaccine Symposium, Bethesda, MD, February 5, 2006.
- 5. "A pilot study of PANVAC-V and PANVAC-F in patients with metastatic carcinoma." Oral presentation, Developmental Therapeutics: Immunotherapy Session, 2006 ASCO Annual Meeting, Atlanta, GA, June 4, 2006.
- 6. "A phase I study of an intratumoral poxviral vector vaccine encoding PSA and multiple costimulatory molecules in locally recurrent prostate cancer." Mary Crowley Medical Research Center Excellence Award speaker. 14th International Conference on Gene Therapy of Cancer, Dallas, Texas, September 15, 2006.
- 7. "Recent clinical advances in cancer vaccines." Lecture at the European Society of Medical Oncology (ESMO)/Biotherapy Development Association (BDA) joint symposium on clinical development of anticancer vaccines, 31st Annual ESMO Congress, Istanbul, Turkey, October 1, 2006.
- 8. "Combining a recombinant cancer vaccine with standard definitive radiotherapy in patients with localized or locally advanced prostate cancer." Lecture to the joint meeting of the Radiation Research Society and ASTRO, Philadelphia, PA, November 7, 2006.
- 9. "The future role of cancer vaccines." Lecture to Blood Services Section meeting/inservice, Department of Transfusion Medicine, NIH, Bethesda, MD, December 12, 2006.
- 10. "A randomized study of 153Sm-EDTMP (Quadramet) with or without a PSA/TRICOM vaccine in men with androgen-independent prostate cancer metastatic to the bone." Presentation to the 2007 Innovative Minds in Prostate Cancer Today (IMPaCT) Meeting, Atlanta, GA, September 7, 2007.
- 11. "The promise of vaccine therapy for cancer." An invited plenary session oral presentation to the 2007 Asia Pacific Conference on Cancer Diagnosis, Therapeutics and Research. General Hospital of the Chinese People's Liberation Army, Beijing, China. September 15, 2007.

- 12. "Status of prostate cancer vaccines." Oral presentation at the 3rd Annual African American Prostate Cancer Disparity Summit, Rayburn House Office Building, Washington, DC, September 28, 2007.
- 13. "Novel combination approaches to immunotherapy for prostate cancer." An invited oral presentation to the International Symposium on Cancer Biology at the National Institute of Immunology, New Delhi, India, November 16, 2007.
- 14. "Adding radiation to ipilimumab: starting the fire for an immune accelerant?" Invited discussant for the ASCO Clinical Science Symposium abstract entitled "Phase I trial of ipilimumab alone and in combination with radiotherapy in patients with metastatic castration-resistant prostate cancer." American Society of Clinical Oncology Annual Meeting, Chicago, IL, June 2, 2008.
- 15. "Immunotherapy for prostate cancer: training your immune system to fight cancer." Keynote address for the Prostate Symposium, Worcester, MA, September 8, 2008.
- 16. "Exploring the synergy of radiotherapy and immunotherapy." Invited faculty presentation at American Society of Therapeutic Radiation Oncology's 50th Annual Meeting. Boston Convention and Exhibition Center, Boston, MA, September 21, 2008.
- 17. "Exploring the synergy of radiotherapy and immunotherapy." Invited faculty presentation at the 2008 Translational Advances in Radiation Oncology and Cancer Imaging Symposium, sponsored by the American Society of Therapeutic Radiation Oncology, Westin Arlington Gateway Hotel, Arlington, VA, October 18, 2008.
- 18. "CEA tarmogen: recombinant Saccharomyces cerevisiae-CEA." Lecture at the 9th Annual Targeted Therapies of the Treatment of Lung Cancer meeting hosted by the International Association for the Study of Lung Cancer, Fairmont Miramar Hotel, Santa Monica, CA, February 19, 2009.
- 19. "Career options in government." Invited lecture as a faculty member, American Society of Clinical Oncology Meeting, Orlando, FL, May 30, 2009.
- 20. "PSA-TRICOM immunotherapy for prostate cancer: survival data and a new paradigm." Lecture at the Meeting on Cancer Drug Development, Robinson College, Cambridge University, Cambridge, UK, June 30, 2009.
- 21. "Therapeutic vaccines for prostate cancer: what survival data is teaching us about selecting patient populations." Lecture as faculty member to the Vaccine Development Forum, Boston, MA, September 23, 2009.
- 22. "Controversies regarding time to progression and overall survival data in randomized therapeutic vaccine trials in advanced prostate cancer." Prelude to a panel discussion at the 16th Annual Prostate Cancer Foundation Meeting, Lake Tahoe, NV, September 25, 2009.

- 23. "Immunotherapy for prostate cancer: survival data and a new paradigm." Lecture at Vaccines: All Things Considered Conference, Crystal City, VA, November 9, 2009.
- 24. "Therapeutic vaccines for prostate cancer." Plenary session lecture at the AACR-sponsored Translational Cancer Medicine 2010, Amsterdam, The Netherlands, March 21, 2010.
- 25. "Immunotherapy: advances in understanding of trial design and patient selection." Lecture to 1st Annual NCI/Prostate Cancer Foundation Meeting, North Bethesda Marriott, April 6, 2010.
- 26. "Prostate cancer and the role of vaccines: the dawn of a new age." Keynote lecture at the PROSTVACTM Update Meeting, in concert with the annual international BIO Meeting, hosted by Bavarian Nordic, Studio VI at Hotel W, Chicago, IL, May 6, 2010.
- 27. "Immunotherapy for prostate cancer." Lecture at the Prostate Cancer Foundation/Department of Defense Prostate Cancer Clinical Trials Consortium (PCCTC) meeting, in concert with the annual ASCO meeting, Chicago, IL, June 3, 2010.
- 28. "Prostate cancer and the role of vaccines: the dawn of a new age." Keynote lecture at the PROSTVACTM Update Meeting, in concert with the annual ASCO meeting, hosted by Bavarian Nordic, City Center Hotel W, Chicago, IL, June 5, 2010.
- 29. "Therapeutic vaccines: advances in understanding of appropriate patient selection and trial design." Invited lecture to the Third Annual Accelerating Proof-of-Concept Conference, sponsored by the Cambridge Healthtech Institute, Philadelphia, PA. October 5, 2010.
- 30. "PROSTVAC: a promising new therapeutic vaccine for prostate cancer." Invited lecture to the Cancer Immunotherapy Key Opinion Leaders meeting, New York, NY. October 21, 2010.
- 31. "Prostvac in castration-resistant prostate cancer." Lecture at Chemotherapy Foundation Symposium meeting on Innovative Cancer Therapy for Tomorrow, New York, NY. November 12, 2010.
- 32. "Overview of Metastatic Prostate." Invited lecture to the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting on Sipuleucel-T (Provenge), Baltimore, MD. November 17, 2010.
- 33. "Therapeutic Vaccines and Immunotherapy: The Dawn of a New Era." A brief overview at the Cancer Vaccines & Immunotherapeutics session, Strategies for Clinical Oncology Drug Development meeting, San Francisco, CA. February 23, 2011.

- 34. "What immunotherapy clinical trials are telling us about meaningful endpoints and appropriate patient populations." Cambridge Healthtech Institute, San Francisco, CA. February 25, 2011.
- 35. "Emerging Data on Meaningful Endpoints and Appropriate Patient Populations for Therapeutic Vaccine Clinical Trials." Tokyo, Japan. March 10, 2011.
- 36. "Metronomic low-dose IL-2 and other immunotherapies combined with cancer vaccines." Cancer Immunotherapy Consortium. Gaylord National Hotel & Convention Center, National Harbor, MD. March 17, 2011.
- 37. "Recent advances in pox viral therapeutic vaccines for cancer treatment." Immunotherapy of Cancer Event, Copenhagen, Denmark. April 27, 2011.
- 38. "PROSTVAC: a promising new therapeutic vaccine for prostate cancer." Invited lecture to the Association for Cancer Immunotherapy (CIMT), Mainz, Germany. Scheduled for May 25, 2011.
- 39. "Blocking 2 pathways better than 1?: It's a START." A review of an oral presentation as an invited discussant (and chair) of the Personalized Medicine session within the Clinical Science Symposium at the 2011 Annual Meeting of ASCO, Chicago, IL. Scheduled for June 3, 2011.
- 40. "Recent advances in pox viral therapeutic vaccines for cancer treatment." A lecture at an ASCO satellite symposium on Prostate Cancer Treatment, Chicago, IL. Scheduled for June 5, 2011.
- 41. "Selection of Patients for Therapeutic Vaccine Clinical Trials." A lecture at the annual ImVacs meeting, Boston, MA. Scheduled for August 17, 2011.
- 42. "Combining vaccines with other therapeutics: a strategy to accelerate proof-of-concept studies?" Society for Immunotherapy of Cancer Annual Meeting (chair and talk). Bethesda North Marriott, Bethesda, MD. Scheduled for November 6, 2011.
- 43. "Therapeutic vaccines." Symposium talk, New Delhi, India. Scheduled for November 14, 2011.